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(71)(72) Applicant and Inventor: KELLEHER, Brian, S. [US/US]; 733 Genter Street, La Jolla, CA 92037 (US).

(74) Agents: BERG, Richard, P. et al.; Ladas & Parry, Suite 2100, 5670 Wilshire Boulevard, Los Angeles, CA 90036 (US).

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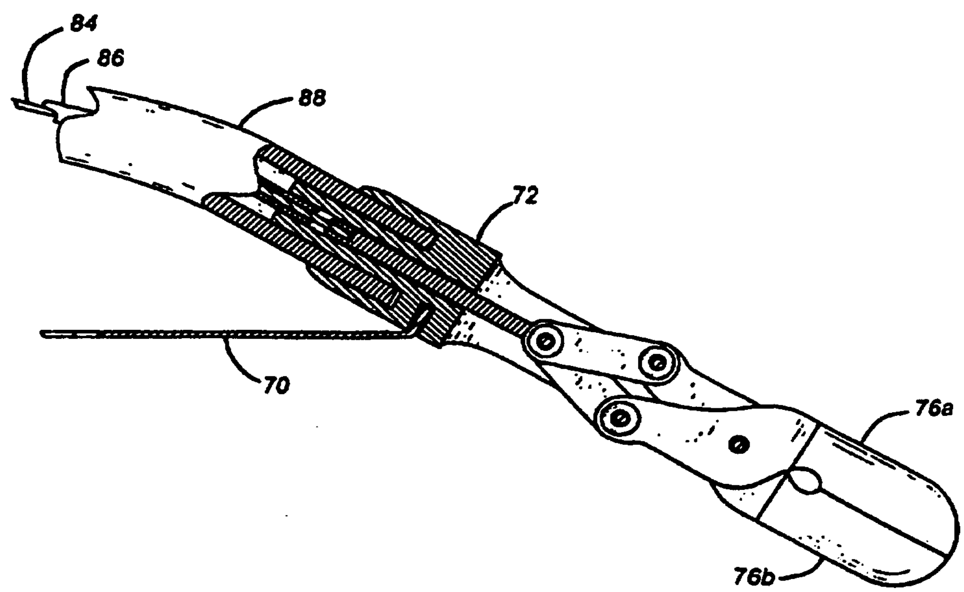
(57) Abstract



A flexible forceps device includes an elongated, flexible body, a control assembly adjacent to the proximal end of the flexible body, and an effector assembly coupled to the distal end having a support piece and at least one movable element. A coaxial actuating assembly extends through a lumen of the flexible body and includes a flexible, hollow tube and a control wire. The hollow tube is substantially incompressible along its long axis and is coupled at its proximal end to the control assembly and at its distal end to the effector assembly. The control wire extends through the hollow tube and is linked at its proximal end to the control assembly and at its distal end to the effector assembly. A steering control means extends at least partially through a lumen in the flexible body and is linked at its proximal end to the control assembly and at its distal end near the distal end of the flexible body. Axial movement of the control wire by the control assembly results in movement of at least one movable element in the effector assembly relative to the support piece, with little movement of the flexible body. Axial movement of the steering control means by the control assembly results in lateral deflection of the flexible body with little movement of any movable elements in the effector assembly relative to the support piece. The hollow tube may optionally function as the steering control means. Further adaptations include torsional-stiffening means and sealing means.

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STEERABLE, FLEXIBLE FORCEPS DEVICE

Background of the Invention

1. Field of the Invention

This invention relates to the field of medical instrumentation and more specifically to the field of elongated, flexible forceps devices for grasping, cutting, removing or otherwise manipulating tissues and other materials inside a patient.

2. Description of the Prior Art

Devices for manipulating tissue are frequently used in minimally-invasive surgical and diagnostic procedures. Such procedures typically involve the use of an endoscope, which allows visualization of inner structures of a patient without the need for conventional surgery. Manipulation of tissue is accomplished by passing specialized accessories through a hollow channel of the endoscope into the inner cavity of the patient. These accessories perform functions such as cutting, grasping, snaring, dissecting, cauterizing and tissue sampling. The present invention relates specifically to accessories for flexible endoscopes, which are used for procedures involving passageways such as the intestine and esophagus. In particular, the present invention relates to flexible endoscopic accessories such as forceps, that have movable elements located at the distal end.

Conventional forceps are comprised of an effector assembly at the distal end, a control assembly at the proximal end, and a tightly wound spring-coil extending between the distal and proximal ends. An actuating force is generated at the proximal end by a push-pull mechanism in the control assembly. This force is transmitted to the distal end by pushing or pulling on one or more control wires extending through the lumen of the spring-coil to the effector assembly. The effector assembly is comprised of a support piece and one or more effectors. The effectors are

fashioned for the specific function of the device, such as grasping, cutting or tissue sampling. Typically, the effectors comprise a pair of jaws that pivot about a fixed hinge-pin on the support piece. The control wires are linked to the jaws, causing the jaws to open or close as a result of pushing or pulling on the control wires. Examples of such devices are disclosed in U.S. Pat. Nos. 5,133,727 (Bales) and 3,964,468 (Schulz).

Conventional forceps utilize a spring-coil body design because the spring-coil is very flexible, allowing it to conform to the tortuous path that may be traversed by a flexible endoscope. Typically, the body of a forceps device must be able to bend to a radius of one inch or less without permanently deforming. Further, the spring-coil enshrouds the control wire and protects it from kinking. Most importantly, the spring-coil is relatively incompressible along its long axis, providing an effective column support between the control assembly and the effector assembly. Thus, the control wire may be tensioned without significant reduction in length of the spring-coil.

Despite these benefits, the spring-coil presents two problems to the user. First, although the spring-coil is relatively incompressible along its long axis, its bending stiffness can increase dramatically when the control wire is tensioned. As a result, tensioning of the control wire can cause a slight repositioning of the spring-coil within the channel of the endoscope as the bending stiffness of the spring-coil increases. This repositioning can cause unwanted movement of the distal section, significantly interfering with accurate manipulation of the forceps during jaw closure.

The second problem with the spring-coil involves cleaning. During a procedure, it is common for the spring-coil to become contaminated with patient fluids containing blood, mucous and feces. Using conventional cleaning procedures, it is difficult to remove all of the patient material from the crevices and inner surfaces of the spring-coil. Such residual contamination presents the potential for microbial and viral cross-contamination between sequential patients.

Solutions to these problems are disclosed in commonly-owned and co-pending U.S. Patent Application "Flexible Forceps Device," which teaches the construction of a flexible forceps

device wherein the conventional spring-coil is replaced with a coaxial actuating assembly surrounded by a smooth-surfaced extruded jacket. The coaxial actuating assembly is comprised of a flexible, thin-wall tube, preferably made of stainless steel, and has a control wire extending through its lumen. The bending stiffness of a forceps device based on the coaxial actuating assembly remains relatively constant during actuation of the forceps. Also, by potentially eliminating the spring-coil, the cleaning problem can be greatly simplified.

When conventional flexible forceps are used with a typical front-viewing endoscope, the forceps are pushed through the hollow channel of the endoscope until they appear in the field of view inside the patient. The tip of the endoscope is then articulated (via steering knobs at the proximal end of the endoscope) such that the tissue or object of interest is directly in front of the endoscope tip. The forceps are then advanced distally until the object of interest is contacted by the forceps effectors.

In some situations, it is nearly impossible to position the object of interest in front of the endoscope tip. For example, when a flexible endoscope is inserted into the human esophagus, the wall of the esophagus is essentially orthogonal to the front face of the endoscope. The small diameter of the esophagus limits angulation of the endoscope tip, making it very difficult to contact the esophagus wall with the forceps effectors. In these situations, it would be desirable to have the ability to deflect the distal portion of the forceps device to a desired angle relative to the long axis of the endoscope. It would further enhance the utility of such a forceps device if the radial orientation of the distal end could also be controlled, thereby allowing the forceps tip to be deflected and then rotated to any location within the endoscopic field of view.

Achieving rotational control of the forceps body is easily achieved with rigid devices, as disclosed in U.S. Pat. Nos. 5,281,220 (Blake), 5,275,613 (Haber), and 5,330,502 (Hassler). However, with a conventional spring-coil body design, simple twisting of the body at the proximal end does not translate into accurate radial movement of the distal end, due to a lack of torsional stiffness of the body. Thus, twisting at the proximal end causes a winding-up of the body until a

certain point is reached, after which the body sporadically unwinds. Means for improving the torsional stiffness of such an elongated, flexible body are well-known in the art and typically involve the addition of layers of braided filaments to the flexible body. Examples include U.S. Pat. Nos. 2,962,050 (Ramberg), 3,485,234 (Stevens), 4,425,919 (Alston), 4,586,923 (Gould) and 4,817,613 (Jaraczewski). Materials commonly used for the braided layer include round wire, flat wire and synthetic cord. Alternatively, a thin layer of torsional-stiffening material may be applied to the flexible body, as disclosed in U.S. Pat. No. 4,945,920 (Clossick).

Achieving the goal of tip-deflection for a flexible forceps device is more difficult. One approach is to construct a specialized endoscope that has provisions for deflecting the distal portion of an endoscopic accessory. U.S. Patent No. 4,653,476 (Bonnet) discloses a uretero-renoscope having an insertion portion which can steerably deflect a flexible auxiliary instrument. U.S. Patent No. 4,245,624 (Komiya) discloses an endoscope having a bendable guide tube slidably disposed within a channel of the endoscope. While each of these designs offers a means for deflecting the distal portion of a flexible accessory, they both require the use of a specialized endoscope. It would be preferable for the forceps device to have a self-contained deflection mechanism such that the device could be used either independently or in conjunction with a conventional endoscope.

Rigid endoscopic accessory devices that offer self-contained deflection mechanisms are disclosed in U.S. Pat. Nos. 5,209,747 (Knoepfler), 5,330,502 (Hassler) and 5,275,608 (Forman). In U.S. Pat. No. 5,354,311 (Kambin), a rigid-shaft forceps device has a spring-coil distal section that is laterally deflected by tension applied to a pair of pull-wires. A semi-flexible forceps design having articulation capabilities is disclosed in U.S. Pat. No. 4,880,015 (Nierman). Nierman '015 has a flexible main body with a pivoting rigid distal section, but the fixed length of the distal pivot arm limits the versatility of the device.

In Clossick '920, a flexible forceps device is disclosed having a spring-coil body that has a covering made of a formable material allowing the spring-coil to be pre-formed to a desired

bend angle prior to insertion into an endoscope. The disadvantage of this approach is that the operator has no control over the bend angle once the forceps have been inserted into the endoscope.

Endoscope-type articulation mechanisms, such as those disclosed in U.S. Pat. Nos. 3,778,304 (Takahashi), 4,353,358 (Emerson), 4,911,148 (Sosnowski), 5,318,526 (Cohen), and 5,325,845 (Adair) are not designed to hold their position when an axial compressive load is applied to the body of the device. The distal end of a forceps device constructed with these types of deflection mechanisms would move out of position during tensioning of the control wire. Similarly, catheter-type steering mechanisms based on spring-coil body designs such as disclosed in U.S. Pat. No. 5,308,324 (Hammerslag) would also exhibit unwanted movement of the tip region under a compressive load. U.S. Pat. No. 5,306,245 (Heaven) discloses an articulating device for endoscopic accessories that is said to withstand end-loading. However, Heaven '245 is configured only for rigid endoscopic applications and teaches no flexible adaptations.

Alternative methods of deflecting the tip of a flexible cannula or endoscopic accessory are disclosed in U.S. Pat. No. 5,318,528 (Heaven) and WO92/14506 (Middleman). Heaven '528 comprises a pair of flexible, pre-curved tubular members, disposed such that one member slidably surrounds the other. By varying the relative radial and axial orientations between the tubular members, it is claimed that the tip can be guided to any desired position. The Heaven '528 mechanism may be used as a guide tube to surround and steer a forceps device, or as a self-contained forceps device having a pair of graspers disposed at the distal end of the tubular pair. In either case, the Heaven '528 device requires the addition of at least one extra layer to the circumference relative to a conventional forceps design, making the Heaven '528 less adaptable for smaller-diameter endoscopic applications. Middleman '14506 discloses a flexible, tubular body slidably surrounding a pre-bent elastic member and a straightener. By altering the relative axial orientation of the elastic member and straightener, the distal region of the tubular

body can be variably deflected. The Middleman '14506 mechanism has the same problem with axially compressive loads as do conventional spring-coil designs.

There is, therefore, a need for a self-contained flexible forceps device having a body portion whose distal end can be deflected to a desired bend angle by manipulating controls located at the proximal end. It is further desirable for the flexible body to undergo relatively little unwanted movement during actuation of the movable elements in the effector assembly. Similarly, it is desirable for the effector assembly to undergo relatively little unwanted movement during deflection of the flexible body. It is also desirable for the flexible body to have torque transmitting properties. Preferably, such a flexible forceps device should be easy to clean, relatively inexpensive to produce and easy to use.

Summary of the Invention

In accordance with the present invention, there is provided a flexible forceps device including an elongated, flexible body, a control assembly adjacent to the proximal end of the flexible body, and an effector assembly coupled to the distal end having a support piece and at least one movable element. A coaxial actuating assembly extends through a lumen of the flexible body and includes a flexible, hollow tube and a control wire. The hollow tube is substantially incompressible along its long axis and is coupled at its proximal end to the control assembly and at its distal end to the effector assembly. The control wire extends through the hollow tube and is linked at its proximal end to the control assembly and at its distal end to the effector assembly. A steering control means extends at least partially through a lumen in the flexible body and is linked at its proximal end to the control assembly and at its distal end near the distal end of the flexible body. Axial movement of the control wire by the control assembly results in movement of at least one movable element in the effector assembly relative to the support piece, with little movement of the flexible body. Axial movement of the steering control means by the control assembly results in lateral deflection of the flexible body with little movement of any movable elements in the effector assembly relative to the support piece. The hollow tube may optionally function as the steering

control means. Further adaptations include torsional-stiffening means and sealing means.

The effector assembly includes at least one movable element coupled to a relatively rigid support piece, such that the movable element can move relative to the rigid support piece. The distal end of the control wire is linked to the movable element, and the distal end of the hollow tube portion of the coaxial actuating assembly is attached to the rigid support piece. The proximal ends of the hollow tube and control wire are coupled to a first push-pull element in the control assembly. Movement of the first push-pull element in the control assembly causes movement of the control wire relative to the hollow tube portion of the coaxial actuating assembly and thereby causes movement of the movable element of the effector assembly relative to the rigid support piece. Since the hollow tube portion of the coaxial actuating assembly is substantially incompressible, tension on the control wire does not alter the position of the effector assembly relative to either the flexible body or the control assembly.

The distal end of the steering control means is linked to the rigid support piece of the effector assembly. The proximal ends of the steering control means and flexible body of the forceps device are attached to a second push-pull control element in the control assembly. This second push-pull control element allows pulling or pushing of the proximal end of the steering control means relative to the proximal end of the flexible body of the forceps. Such pulling or pushing of the steering control means places the flexible body in compression or tension, respectively. The flexible body is configured to respond to compression or tension by bending in a predictable direction.

In one embodiment, the coaxial actuating assembly is centrally disposed within the lumen of the flexible body and the effector assembly includes a conventional center-pull mechanism. Pulling and pushing on the control wire relative to the hollow tube portion of the coaxial actuating assembly causes movement of the movable elements in the effector assembly. Since the hollow tube is substantially incompressible along its long axis and since the bending stiffness of the coaxial actuator remains relatively constant during pulling or pushing of the control wire, the

orientation of the flexible body is relatively unaffected by such pulling or pushing. The steering control means comprises a wire extending through the main length of the lumen of the flexible body and exits through an aperture in the wall of the flexible body. The distal end of the steering wire is anchored in the rigid support piece of the effector assembly. The length of the flexible body between the aperture and the effector assembly defines the intended bending region. Pulling on the steering wire causes deflection of the bending region from the anchoring point toward the aperture. The advantage of this arrangement is that a large amount of deflection can be achieved with a relatively small amount of force on the steering wire. The disadvantages are: 1) a high concentration of bending stress occurs at the anchoring point of the steering control wire in the rigid support piece, 2) it is difficult to effectively seal the aperture in the wall of flexible tube, 3) the exposed length of steering wire may become snared on biological or mechanical structures, and 4) when used with an endoscope, the length of exposed steering wire may damage the distal rim of the working channel.

One solution to the stress-concentration problem at the anchoring point of the steering wire is to use a fine-wire stranded cable or a synthetic cord such as Kevlar (trademark of E. I. DuPont Co., Wilmington, DE). Another solution is to anchor the steering wire to a pivoting element linked to the rigid support piece. In one embodiment, a side-pull effector assembly is adapted to include a pivoting steering wire anchoring element.

To alleviate the problems of the exposed length of steering wire, the wire can be contained entirely within a lumen of the flexible body. However, in order for a bending moment to be applied to the distal region of the device, there must be a separation between the anchoring points of the hollow tube and the steering wire – the greater the separation, the greater the bending moment for a given pulling force on the steering wire. Thus, in many of the embodiments presented, a side-pull effector assembly is illustrated, wherein the coaxial actuator is offset from the central axis of the flexible body.

In one embodiment, the coaxial actuator extends through a first lumen of the flexible body

and the steering wire extends through a second lumen. Pulling on the steering wire causes the flexible body to deflect toward the side on which the steering wire is anchored. The advantage of this approach is that the device is easier to seal, and thus easier to clean, than the exposed steering wire embodiment. The primary disadvantage is that the full length of the flexible body is compressed and therefore deflects as the steering wire is pulled. The full-length deflection is undesirable in applications where a surrounding tubular constraint, such as the channel of an endoscope, is not present. Also, the compression of the flexible body results in a decrease in length and a subsequent unwanted movement of the distal end. An additional disadvantage is that a relatively large amount of force is needed to generate deflection, and a lower maximum deflection is achievable relative to the exposed steering wire embodiment.

Many conventional techniques are available for concentrating the deflection to a desired region of the flexible body. Such techniques typically involve altering the physical arrangement and material properties of elements in the target bending region such that applied compression or tension will result in predictable deflection. However, forces applied to the effector mechanism must be isolated from the deflection mechanism, otherwise unwanted movement of the flexible body will occur during actuation of the effector assembly. Such isolation can be achieved by using the coaxial actuating assembly to transmit actuating forces to the effector assembly.

In one embodiment, the coaxial actuating assembly and steering wire are disposed in a large central lumen of the flexible body. The flexible body is made of a pliant material and has notches disposed along one edge of the desired bending region, on the side closest to the anchor point of the steering wire. Thus, pulling on the steering wire causes the flexible body to bend toward the notched side. With the notches, the force required to achieve deflection is lower and the maximum amount of deflection that can be achieved is greater than that which can be achieved without notches. The disadvantage of the notched approach is that the device is more difficult to clean and the notches can pinch tissue during deflection. One solution is to cover at least the bending portion of the flexible body with a thin layer of elastomeric material. Another disadvantage of the notched approach is that the full length of the flexible body undergoes

compression, resulting in a decrease in length and unwanted movement of the distal end.

An embodiment that addresses the problem of unwanted movement of the distal end utilizes a spring-coil flexible body. The spring-coil has tightly wound adjacent segments for the main length of the flexible body, making it essentially incompressible. In the bending region, the spring-coil has a wider pitch, making it somewhat compressible. As in the previous embodiment, the coaxial actuating assembly and steering wire are offset from the central axis of the flexible body. With this arrangement, pulling on the steering wire causes the spring-coil to compress more along the side on which the steering wire is anchored, resulting in deflection in that direction. The advantage of this embodiment is that the main length of the flexible body does not decrease in length, thus no unwanted movement of the distal end occurs. The disadvantage is the difficulty in cleaning the spring-coil.

In a different embodiment, the flexible tube has a large central lumen through which both the coaxial actuating assembly and steering wire extend. As in previous embodiments, a side-pull effector assembly is used such that the anchoring sites for the coaxial actuating assembly and steering wire can be separated. In the bending region, the coaxial actuating assembly and steering wire maintain this separation. At the proximal end of the bending region, the coaxial actuating assembly jogs over to the steering wire side. Throughout the remaining length of the flexible tube, a guide core is disposed within the lumen. The guide core fills the lumen except for a single channel extending along one edge to accommodate both the coaxial actuating assembly and the steering wire. The hollow tube portion of the coaxial actuating assembly is bonded to the guide core, which in turn is bonded to the flexible body. The steering wire can slide freely in the guide core channel. A sleeve may be slidably disposed around the steering wire to simplify assembly and to improve performance. With this configuration, the separation between the coaxial actuator and steering wire results in a concentration of deflection within the bending region. In the main length of the flexible body, the incompressibility of the hollow tube portion of the coaxial actuating assembly prevents a decrease in length of the flexible body when the steering wire is tensioned.

Alternatively, the deflecting force may be applied by pushing instead of pulling on the steering control means. Different deflection characteristics may be imparted to the device by disposing various restraining means into or upon the flexible body. Such techniques are disclosed in co-pending and commonly-owned U.S. Patent Application "Deflectable Medical Device." The restraining means prevent portions of the flexible body from stretching as a result of tension applied by the pushing force on the steering control means. The restraining means may take the form of a stretch-resistant layer disposed upon, or incorporated within, portions of the flexible body. Similarly, the restraining means may be formed from filaments disposed along the long axis of the flexible tube. The restraining means may be disposed only along certain portions of the flexible tube or they may be disposed along the full length and then selectively trimmed.

In one embodiment, the steering control means comprises a push-wire disposed within a first lumen of the flexible body, and the coaxial actuating assembly is disposed within a second lumen. As in previous embodiments, a side-pull effector assembly is included such that the coaxial actuating assembly and steering wire may be separated. A restraining layer is disposed over the entire flexible body except for the steering wire side of the bending region. With this arrangement, pushing on the steering wire places the flexible body in tension. Since the unrestrained portion of the bending region is the only portion of the flexible body that may stretch, the bending region deflects away from the steering wire side. The advantages of this approach are the simplicity of construction and ease of cleaning.

Each of the embodiments presented thus far illustrates means for deflecting the flexible body in a single plane. However, for maximum clinical utility, the operator should be able to move the distal tip of the device to any location within a 360-degree field. One method for achieving such control is to add multiple steering wires. Two wires would give the device either bilateral movement in a single plane or unilateral movement in two planes. Three or more steering wires would provide the desired full range of control. The control assembly would need

to be modified to have an omni-directional control member such as a joystick, using methods well-known to those skilled in the art.

Another way of achieving 360-degree control of tip location is to add rotational control of the flexible body to embodiments having single-plane deflection. However, simple twisting of the flexible body at the proximal end does not provide for accurate rotational control of the distal end, due to a lack of torsional stiffness of the body. To improve the torsional stiffness of a spring-coil body, a layer of flexible, tight-fitting material can be added by a process such as heat-shrinking. To improve the torsional stiffness of a pliant, extruded body, a layer of torsionally-stiff material may be disposed around the flexible body. Alternatively, a layer of filaments, such as flat-wire stainless steel or Kevlar, may be wrapped or braided around the outside of the flexible body. The torsional-stiffening layer may be sealed with a coating such as polyurethane or covered with a flexible, heat-shrinkable tubing. One or more torsional-stiffening layers may be applied to any of the embodiments disclosed herein.

In a different embodiment, the coaxial actuating assembly is slidably disposed within a lumen of the flexible body, and a side-pull effector assembly is attached to the distal end. A braided torsional-stiffening layer is disposed along the full length of the flexible body, except in the bending region. Integrated with the torsional-stiffening layer are restraining filaments, disposed in parallel with the long axis of the flexible body. Along the side of the bending region farthest from the coaxial actuating assembly, the restraining filaments extend to the distal end of the flexible body. The hollow tube portion of the coaxial actuating assembly functions as the steering control means. The control assembly is configured to push the hollow tube axially relative to the flexible body, placing the flexible body in tension. Since the main length of the flexible body is restrained, no stretching occurs. However, the side of the bending region near the coaxial actuating assembly is allowed to stretch, causing the bending region to deflect toward the opposite side. The principal advantage of this configuration is its simplicity and reduced number of parts. Various modifications may be made to the bending region to enhance the deflection behavior, such as notches on the coaxial actuating assembly side of the flexible body.

In yet another embodiment, two coaxial actuators are disposed within the flexible body, each within a separate lumen. A side-pull effector assembly is actuated by one of the coaxial actuating assemblies. The hollow tube portion of the second coaxial actuating assembly extends from the control assembly to the proximal end of the bending region and is bonded to the lumen of the flexible body. The wire extending through the hollow tube in the second coaxial actuating assembly constitutes the steering wire. With this arrangement, pulling or pushing on the steering wire causes the bending region to be placed in tension or compression, respectively. Since the flexible body is bonded to the hollow tube portion of the second coaxial actuating assembly, the flexible body is restrained from compressing or stretching except in the bending region. This approach offers the advantage of bilateral deflection of the bending region but has the disadvantage of requiring a second coaxial actuating assembly, which adds to cost and increases the bending stiffness of the flexible body.

As disclosed in co-pending and commonly-owned U.S. Patent Application "Flexible Forceps Device," sealing means may be disposed at the proximal and distal ends of the device to prevent contaminating fluids from entering the inner regions of the flexible body. Such sealing means may encompass molded packings, sealing boots, diaphragms, or plugs. In embodiments of the present invention that incorporate a flexible body constructed with a sealed, smooth surface, seals at the proximal and distal ends may be included to make the device easy to re-process between uses. By way of example only, several embodiments disclosed herein include such sealing means.

The control assembly may be constructed in any conventional manner to impart the desired pushing or pulling forces to the actuating elements. Several example embodiments are disclosed to illustrate such construction.

In one control assembly embodiment, a pair of finger spools are slidably disposed along a common shaft. The proximal end of the common shaft has a thumb ring. The finger spools and

thumb ring are shaped to comfortably accept the fingers and thumb, respectively, of the operator. Each spool may be individually operated. A squeezing motion applied by the operator causes each finger spool to slide toward the thumb ring. One finger spool is linked to the effector actuating mechanism, while the other spool is linked to the steering mechanism. A second thumb ring may be attached adjacent to the first thumb ring to allow actuation of both finger spools at the same time, using two hands.

A different approach is to actuate the effector mechanism with a finger spool and to actuate the steering mechanism with a rotating collar. Two embodiments using this approach are disclosed. In the first embodiment, the finger spool is linked to the effector actuating mechanism, while the rotating collar is linked to the steering wire. This approach is compatible with all of the deflection mechanisms disclosed except the one which uses the hollow tube portion of the coaxial actuating assembly as a steering control means. The second embodiment is compatible with the deflection mechanism that uses the hollow tube portion of the coaxial actuating assembly as a steering control means. In this embodiment, the rotating collar is linked to the hollow tube portion of the coaxial actuating assembly. This latter embodiment has the advantages of being simpler and requiring fewer parts than other embodiments.

It is among the general objects of the present invention to provide a self-contained, flexible forceps device having a flexible body that may be controllably deflected by manipulating controls located at the proximal end.

It is another object of the invention to provide a controllably deflectable flexible forceps device having an effector assembly that can be operated without causing deflection of the flexible body.

Yet another object of the invention is to provide a flexible forceps device having a flexible body that may be controllably deflected without causing unwanted movement of the movable elements in the effector assembly.

It is a further object of the present invention to provide a flexible forceps device having a flexible body with torque transmitting properties along its length.

It is another object of the present invention to provide a flexible forceps device that is relatively simple to use and inexpensive to construct.

It is a further object of the present invention to provide a flexible forceps device that is easy to clean.

Brief Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 shows a conventional flexible forceps device without deflection capabilities;

FIG. 2 is an enlarged, perspective view of a flexible forceps device constructed in accordance with the present invention, shown protruding from the working channel of a flexible endoscope inside a body cavity. Two positions, *A* and *B*, of the forceps device are illustrated;

FIG. 3 is a side view of the distal region of a center-pull forceps device constructed in accordance with the present invention;

FIG. 4 is an enlarged view of a segment of the effector assembly of the embodiment illustrated in FIG. 3, with portions broken away to show the underlying layers;

FIG. 5 is an enlarged view of a segment of the bending region of the embodiment shown in FIG. 3, with portions broken away to show the underlying layers;

FIG. 6 is an enlarged view of the distal region of the embodiment illustrated in FIG. 3, showing the steering wire tensioned to cause deflection, with portions broken away to show the

underlying layers;

FIG. 7 shows the embodiment illustrated in FIG. 3 in various stages of deflection, indicated by positions *A* through *D*;

FIG. 8 is an enlarged side view of the effector assembly of a side-pull forceps device constructed in accordance with the present invention, showing the jaws closed and portions broken away to reveal underlying structure;

FIG. 9 is an enlarged side view of the embodiment illustrated in FIG. 8, showing the jaws in their open position;

FIG. 10 is an enlarged side view of the effector assembly of a different embodiment in accordance with the present invention, with portions broken away to show underlying mechanisms;

FIG. 10a is a view of the lever link from the embodiment illustrated in FIG. 10;

FIG. 10b is a view of the steering pivot link from the embodiment illustrated in FIG. 10;

FIG. 10c is a view of the lower jaw from the embodiment illustrated in FIG. 10;

FIGS. 11 through 13 are sectional views of the embodiment illustrated in FIG. 10;

FIG. 14 is an enlarged view of the distal region of the embodiment illustrated in FIG. 10, showing the steering wire tensioned to cause deflection, with portions broken away to show the underlying mechanisms;

FIG. 15 is an enlarged side view of the effector assembly of a different embodiment in accordance with the present invention, with portions broken away to reveal underlying mechanisms;

FIGS. 16 through 18 are sectional views of the embodiment illustrated in FIG. 15;

FIG. 19 shows the distal region of the embodiment illustrated in FIG. 15 in various stages of deflection, indicated by positions *A* through *C*;

FIG. 20a is an enlarged view of the distal region of a different embodiment in accordance with the present invention, with portions broken away to reveal underlying mechanisms;

FIG. 20b shows the embodiment illustrated in FIG. 20a with the steering wire tensioned to cause deflection of the bending region, with portions broken away to reveal underlying mechanisms;

FIG. 21 is a sectional view of the embodiment illustrated in FIG. 20a;

FIG. 22a is an enlarged view of the distal region of a different embodiment in accordance with the present invention, with portions broken away to reveal underlying mechanisms;

FIG. 22b shows the embodiment illustrated in FIG. 22a with the steering wire tensioned to cause deflection of the bending region, with portions broken away to reveal underlying mechanisms;

FIG. 23 is a sectional view of the embodiment illustrated in FIG. 22a;

FIG. 24 is an enlarged view of the bending region of a different embodiment in accordance with the present invention, with portions broken away to reveal underlying mechanisms;

FIGS. 25 and 26 are sectional views of the embodiment illustrated in FIG. 24;

FIG. 27 is an enlarged view of the bending region of a different embodiment in accordance with the present invention, with portions broken away to reveal underlying mechanisms;

FIGS. 28 and 29 are sectional views of the embodiment illustrated in FIG. 27;

FIG. 30 is an enlarged view of the bending region of a different embodiment in accordance with the present invention, with portions broken away to reveal underlying mechanisms;

FIGS. 31 and 32 are sectional views of the embodiment illustrated in FIG. 30;

FIG. 33 is an enlarged view of the bending region of a different embodiment in accordance with the present invention, with portions broken away to reveal underlying mechanisms;

FIGS. 34 and 35 are sectional views of the embodiment illustrated in FIG. 33;

FIG. 36 shows the control assembly from a particular embodiment in accordance with the present invention;

FIG. 37 shows the control assembly from a different embodiment in accordance with the present invention;

FIG. 38 is an enlarged sectional view of the embodiment illustrated in FIG. 37;

FIGS. 39 through 41 are sectional views of the embodiment illustrated in FIG. 38;

FIG. 42 is a view of a portion of the interface region from the embodiment illustrated in FIG. 38;

FIG. 43 is an enlarged sectional view of a modification of the embodiment depicted in FIG. 37;

FIG. 44 is a sectional view through the embodiment illustrated in FIG. 43.

Description of the Preferred Embodiments

The particular embodiments disclosed herein all illustrate flexible biopsy forceps devices. Flexible biopsy forceps are used for removing and recovering samples of tissue from inner cavities of a patient. The forceps are typically inserted through the proximal opening of the working channel of a flexible endoscope until they protrude out the distal face of the endoscope. Biopsy forceps generally have a pair of cupped jaws that pivot from an open position to a closed position, in response to movement of a control wire. Typically, pulling on the control wire closes the jaws, capturing tissue within the cups. After capturing a tissue sample, the forceps device is removed from the endoscope and the tissue sample is taken from the jaws for further analysis. While biopsy forceps may be an appropriate application of the present invention, it will be appreciated that any elongated, flexible medical device with at least one moving effector in the distal region may be constructed using the principles of the present invention. Examples of other appropriate devices include grasping forceps, dissectors, retrieval forceps and cutting forceps. Additionally, the present invention may be applied to accessories for use with industrial borescopes.

FIG. 1 illustrates a conventional flexible biopsy forceps device having no deflection capability. Forceps device 172 comprises control assembly 130, flexible body 64 and effector assembly 66. Control assembly 130 comprises control shaft 138 having forked elements 148a and 148b and interface region 156. Effector assembly 66 is attached to the distal end of flexible body 64. Finger spool 134 is slidably disposed on control shaft 138. Cross-bar 140 extends through a central axis of finger spool 134 and is captured between forked elements 148a and

148b. Thumb ring 132 is disposed at the proximal end of control shaft 138. Typically, an operator slips their thumb through thumb ring 132 and captures finger spool 134 with their index and middle fingers. In this manner, opening and closing movements of the operator's fingers and thumb cause finger spool 134 to slide distally and proximally, respectively, along control shaft 138. In a typical forceps device, cross-bar 140 is coupled to the effector control wire, and flexible body 64 is anchored within interface region 156.

FIG. 2 shows the distal tip of flexible endoscope 50 disposed within a body cavity. The distal face of a typical endoscope includes at least one illumination lens 54, an imaging lens 56, a lens-rinse nozzle 58 and the distal opening to working channel 52. The distal region of most flexible endoscopes is steerable by manipulating controls at the proximal end of the endoscope. With conventional biopsy forceps, it is necessary to angle the endoscope tip to align the target tissue directly in front of the distal face of the endoscope. However, as in the situation shown, the body cavity wall 60 can closely surround endoscope 50, making it difficult to adequately bend the endoscope tip. If a sample of tissue such as polyp 62 is desired, a conventional forceps device, as shown in position *A*, is not able to be correctly positioned. However, a forceps device constructed in accordance with the present invention allows deflection of the tip of the forceps in order to reach polyp 62, as shown in position *B*.

FIG. 3 shows the distal region of a different embodiment in accordance with the present invention. The distal section of flexible body 64 comprises bending region 68 and effector assembly 66, which employs a center-pull actuating mechanism. Steering wire 70 extends along the outside of bending region 68.

FIG. 4 is an enlarged sectional view of the distal portion of the embodiment shown in FIG. 3. Biopsy jaws 76a and 76b pivot about hinge-pin 184 in response to movement of links 176a and 176b, respectively, which are hingedly joined to each jaw and to the distal end of pushrod 178. Jaw support 72 is comprised of outer cylindrical section 98, inner cylindrical section 180 and prongs 74a and 74b (not shown). Hinge-pin 184 is fixedly attached to prongs 74a and 74b

to support jaws 76a and 76b. Pushrod 178 is slidably disposed through the lumen of inner cylindrical section 180. Coaxial actuating assembly 170 is comprised of hollow tube 86 and control wire 84, and is disposed within the lumen of flexible tube 88. Coaxial actuating assembly 170 is preferably constructed in accordance with the specifications disclosed in co-pending and commonly-owned U.S. Pat. Application "Flexible Forceps Device." As such, hollow tube 86 and control wire 84 are both preferably fabricated from stainless steel. Control wire 84 is slidably disposed within the lumen of hollow tube 86 and may have additional means to decrease friction between the wire and tube surfaces. The distal end of hollow tube 86 is attached to inner cylindrical section 180 by means of soldering, brazing, welding, adhesive bonding or the like. The distal end of control wire 84 extends through inner cylindrical section 180 and is fixedly disposed in the proximal end of pushrod 178 by means of crimping, soldering, brazing, welding, adhesive bonding or the like. With this arrangement, movement of control wire 84 within hollow tube 86 causes movement of pushrod 178, which causes links 176a and 176b to move, in turn causing jaws 76a and 76b to open and close. Steering wire 70 is anchored in hole 174 by means of soldering, brazing, welding, adhesive bonding or the like.

While steering wire 70 is shown as being attached to effector assembly 66 in most of the embodiments disclosed herein, it will be appreciated that steering wire 70 may alternatively be anchored directly to flexible body 64 or to a structure affixed within flexible body 64 or the like.

Flexible tube 88 is captured in annular groove 128 and crimped or affixed therein by a resilient adhesive such as silicone or polyurethane to ensure a water-tight seal between flexible tube 88 and jaw support 72. The properties of flexible tube 88 are chosen so as to give flexible body 64 the proper stiffness, kink-resistance and resiliency. It will be appreciated that these properties may be altered not only by material selection and tube geometry, but by stiffening wires, braided layers and the like added to or incorporated within flexible tube 88. For most applications, flexible tube 88 preferably has a relatively lubricous surface so as to ease the process of inserting the device through the channel of an endoscope or the like. As an example, flexible tube 88 may be extruded from a fluoropolymer or fluoroelastomer. Alternatively, flexible

tube 88 may be extruded from a less-expensive polymer such as PVC (polyvinyl chloride) and subjected to a surface modification or coating process to improve lubricity. Surface modifications to improve lubricity include gas plasma treatment (Polar Materials/Wheaton, Inc., Pennsville, NJ) and ion beam deposition (Spire Corporation, Bedford, MA). Lubricous coatings include parylene (Advanced Surface Technology, Inc., Billerica, MA), fluoropolymer (Advance Coating Technology, Mechanicsburg, PA) and various hydrogels (BSI Corporation, Eden Prairie, MN). In at least one embodiment disclosed herein, flexible body 64 is constructed of a flexible spring-coil. The materials and geometries of the spring-coil are described in the detailed description of each particular embodiment. The outer diameter and length of flexible body 64 are dictated by the constraints of the application for which the forceps are intended. For example, flexible endoscopic accessories typically have outer diameters from .02 to .12 inches and lengths from 30 to 100 inches. By way of example only, flexible tube 88 may have an outer diameter of .08 inches and a length of 94 inches.

Jaw support 72, jaws 76a and 76b, and pushrod 178 are substantially intricate parts which are subjected to high stresses. Therefore, the preferred material for these parts is relatively hard metal such as stainless steel. These parts may be fabricated by any of the conventional methods such as machining, metal injection molding, investment casting, powder metallurgy or some combination thereof. Links 176a and 176b may also be fabricated from relatively hard metal and may be formed by a stamping process.

FIG. 5 is an enlarged sectional view of a portion of bending region 68 from the embodiment illustrated in FIG. 3. Flexible tube 88 has an angled aperture 182 allowing steering wire 70 to exit the lumen of flexible tube 88. Between aperture 182 and control assembly 130, both coaxial actuating assembly 170 and steering wire 70 share a common central lumen inside flexible tube 88.

FIG. 6 is the same view as shown in FIG. 4, with steering wire 70 pulled proximally to cause flexible tube 88 to bend. FIG. 7 shows the embodiment of FIG. 3 in various stages of deflection as steering wire 70 is pulled proximally. Steering wire 70 may be formed from a high-

strength solid wire such as stainless steel. However, the high bending stress that occurs near anchoring hole 174 may lead to fatigue and breakage. Thus, steering wire 70 may be fabricated from more flexible materials such as fine stranded stainless steel wire or synthetic cord such as Kevlar. Alternatively, a strain-relief element may be incorporated around steering wire 70 near anchoring hole 174, using techniques well-known to those skilled in the art.

FIG. 8 shows effector assembly 66 of a different embodiment of the present invention. In this embodiment, coaxial actuating assembly 170 is offset from the central axis of flexible tube 88. Jaws 76a and 76b are shown closed, with a portion of jaw 76a removed to reveal the outline of jaw cup 120 and cutting edge 122. FIG. 9 is the same as FIG. 8 with jaws 76a and 76b in their open position.

FIG. 10 is the same embodiment shown in FIG. 8 with portions removed to reveal the side-pull actuating mechanism. This embodiment illustrates two improvements over the embodiment depicted in FIG. 4. First, the spacing between the distal anchoring points of steering wire 70 and coaxial actuating assembly 170 is increased, which increases the bending moment applied to the distal region for a given force on steering wire 70. Second, the distal end of steering wire 70 is attached to pivot link 82 instead of being fixedly anchored in hole 174, thereby eliminating the high-stress problem previously described.

As best seen in FIG. 11, flexible tube 88 has a lumen 90 through which coaxial actuating assembly 170 extends. Steering wire 70 is disposed within groove 92 which extends along the length of bending region 68. Between control assembly 130 and bending region 68, flexible tube 88 may have a second lumen through which steering wire 70 may be slidably disposed. FIG. 13 shows that hollow tube 86 is fixedly disposed in bore 100 of jaw support 72. Groove 94 of jaw support 72 aligns with groove 92 of flexible tube 88 to channel steering wire 70. As seen in FIG. 12, flexible tube 88 is captured by outer cylindrical section 98 and is crimped or affixed therein by a resilient adhesive such as silicone or polyurethane to ensure a water-tight seal between flexible tube 88 and jaw support 72. Referring to FIGS. 10 and 10b, the distal end of

steering wire 70 is coupled to pivot link 82 by bending steering wire 70 through hole 110. Pivot link 82 pivots about hinge-pin 102, which extends through hole 112 and is fixedly attached to prongs 74a and 74b (not shown) of jaw support 72.

Control wire 84 slidably extends though hollow tube 86 and through an aperture in the distal end of bore 100. The distal end of control wire 84 is coupled to lever link 80 by bending control wire 84 through hole 104, referring to FIG. 10a. By way of example, lever link 80 may be fabricated from stainless steel using a stamping process. Recessed area 168 of lever link 80 provides clearance for control wire 84 as lever link 80 pivots around hinge-pin 102, which extends through hole 108. Connecting wire 78 has a V-shaped bend extending through hole 106 of lever link 80. As best seen in FIGS. 10 and 10C, the upper arm of connecting wire 78 is coupled to jaw 76b by bending through hole 114. Recessed area 118 of jaw 76b provides clearance for connecting wire 78 as jaw 76b pivots around hinge-pin 184, which extends through pivot hole 116. Similarly, the lower arm of connecting wire 78 is coupled to jaw 76a. Hinge-pin 184 is fixedly attached to prongs 74a and 74b (not shown) of jaw support 72. With this arrangement, pushing on control wire 84 relative to hollow tube 86 causes lever link 80 to pivot distally. As lever link 80 pivots, connecting wire 78 pushes on both jaws 76a and 76b, causing them to spread open. Likewise, pulling on control wire 84 causes jaws 76a and 76b to close. Connecting wire 78 may be formed from an appropriate material such as high-strength stainless steel or beryllium-copper. Alternatively, connecting wire 78 may be divided into two separate segments, in which case another hole would be needed in lever link 80.

FIG. 14 illustrates the same embodiment from FIG. 10 with steering wire 70 pulled in a proximal direction, showing flexible tube 88 deflecting and pivot link 82 pivoting around hinge-pin 102. When steering wire 70 is released, the combined resilience of flexible tube 88 and coaxial actuating assembly 170 cause the bending region to spring back to its straight shape. It will be appreciated that additional means may be disposed within or upon flexible body 64 to alter or enhance the spring-return behavior of the bending region.

FIG. 15 illustrates an embodiment that overcomes the problems associated with external steering wire 70 in the previous embodiment. In this embodiment, steering wire 70 is fully enclosed by flexible tube 88. As best seen in FIG. 16, steering wire 70 is slidably disposed within lumen 96 of flexible tube 88. To facilitate movement of steering wire 70 within lumen 96, a lubricous coating or surface treatment may be applied to at least one of the outer surface of control wire 70 or inner surface of lumen 96. Alternatively, a lubricant or a sleeve having lubricous properties may be disposed between control wire 70 and lumen 96. Coaxial actuating assembly 170 is disposed within a second lumen 90 of flexible tube 88. A central lumen 124 may also be included in flexible body 88 for such purposes as optimizing flexibility or providing functions such as fluid transfer, imaging, illumination or the like. Alternatively, steering wire 70 and coaxial actuating assembly 170 may be commonly disposed through a single central lumen in flexible tube 88. As best seen in FIG. 17, flexible tube 88 is captured by outer cylindrical section 98 and is crimped or affixed therein by a resilient adhesive such as silicone or polyurethane to ensure a water-tight seal between flexible tube 88 and jaw support 72. Referring to FIGS. 15 and 18, steering wire 70 is fixedly disposed within bore 126 of jaw support 72 by means of soldering, brazing, welding, adhesive bonding or the like. Likewise, hollow tube 86 is anchored in bore 100 of jaw support 72 by similar means. Control wire 84 slidably extends through hollow tube 86 and through an aperture in the distal end of bore 100. The distal end of control wire 84 is coupled to lever link 80. Lever link 80, connecting wire 78 and jaws 76a and 76b function in a manner analogous to that described for the previous embodiment. Thus, pushing and pulling on control wire 84 opens and closes jaws 76a and 76b, respectively.

Pulling on steering wire 70 places flexible tube 88 in compression. Since a greater amount of compression is applied along the steering wire side, flexible body 64 reacts by deflecting toward the steering wire side. This deflection, however, is distributed along the full length of flexible body 64. In order to concentrate the deflection to the bending region, as depicted in FIG. 19, either an internal stiffener is required along the non-bending length, or an external tubular constraint is needed, such as that provided by an endoscope channel. Also, as a result of the axial compression applied to flexible tube 88, some decrease in length of flexible

body 64 occurs, resulting in unwanted proximal movement of the distal region.

FIG. 20a illustrates a different embodiment directed at concentrating deflection to a specific bending region. This embodiment is similar to the previous embodiment, except flexible tube 88 has a single lumen in which both coaxial actuating assembly 170 and steering wire 70 are disposed. As best seen in FIG. 21, hollow tube 86 and steering wire 70 are anchored in bores 100 and 126, respectively. Referring to FIG. 20a, notches 186 are formed along the steering wire side of flexible tube 88 throughout the length of bending region 68. With this configuration, pulling on steering wire 70 causes flexible tube 88 to buckle at each notch, thereby deflecting toward the steering wire side, as shown in FIG. 20b. A smaller amount of force is required to generate a given amount of deflection with this embodiment relative to the previous embodiment, so the problem of unwanted movement of the distal region due to compression of flexible tube 88 is reduced. It will be appreciated that many other techniques may be employed for weakening the steering wire side of flexible tube 88 in bending region 68. Such methods may include thinning the wall of flexible tube 88 on the steering wire side or adding convolutions to the steering wire side, as in a bellows. Alternatively, the opposite side of flexible tube 88 may be strengthened, as by addition of a stiffening element.

Yet another embodiment is directed at further reducing the amount of unwanted movement of the distal region of the device as a result of compression of flexible tube 88 during tensioning of steering wire 70. As shown in FIG. 22a, this embodiment uses the same side-pull mechanism and jaw support 72 as in the previous embodiment. As best seen in FIG. 23, hollow tube 86 and steering wire 70 are anchored in bores 100 and 126, respectively. Referring to FIG. 22a, it can be seen that flexible body 64 is constructed from a spring-coil 188. Between control assembly 130 and bending region 68, spring-coil 188 is formed with tightly-wound adjacent segments, making it essentially incompressible. In bending region 68, however, the pitch of spring-coil 188 is increased, making this portion somewhat compressible. As a result, pulling on steering wire 70 results in deflection of bending region 68 toward the steering wire side, as seen in FIG. 22b. Since the non-deflecting portion of spring-coil 188 is incompressible,

there is minimal unwanted movement of the distal region during tensioning of steering wire 70. By way of example only, spring-coil 188 may be formed from stainless steel wire having a diameter between about .010 and .020 inches. The deflection profile may be altered by varying the coil pitch or wire characteristics within bending region 68. Additionally, hollow tube 86 can be fixedly attached to one or more segments of spring-coil 188 to provide increased stiffening. For example, hollow tube 86 may be attached to the inner surface of spring coil 188, at point *A* as indicated in FIG. 22a. Such a configuration would help to prevent bending region 68 from decreasing in length as steering wire 70 is tensioned, further reducing unwanted movement of the distal region.

FIG. 24 illustrates a different embodiment having features directed at reducing the amount of unwanted movement as a result of compression of flexible tube 88, without using a spring-coil body. Flexible tube 88 has single central lumen 124 surrounding both coaxial actuating assembly 170 and steering wire 70. The side-pull effector portion of the device is similar to that described in previous embodiments, having hollow tube 86 and steering wire 70 anchored on opposite sides of jaw support 72. Throughout bending region 68, coaxial actuating assembly 170 and steering wire maintain this separation, in order to maximize the applied bending moment, as best seen in FIG. 26. However, near the proximal end of bending region 68, coaxial actuating assembly 170 gradually veers over to the steering wire side, as illustrated in FIG. 24. Guide core 190 is disposed within lumen 124 between control assembly 130 and the proximal end of bending region 68. As best seen in FIG. 25, guide core 190 has a groove extending axially along the steering wire side, sized to tightly accommodate coaxial actuating assembly 170. Hollow tube 86 is bonded to the groove of guide core 190 with a resilient adhesive such as silicone, polyurethane or other adhesive having good flexibility and high shear strength. Likewise, guide core 190 is bonded to lumen 124 with a similar adhesive. Steering wire 70 is slidably disposed in the space defined by the wall of lumen 124, the walls of the groove in guide core 190 and the outer surface of hollow tube 86. To enhance slidable movement of steering wire 70 within this space, thin-wall sleeve 192 may be disposed around steering wire 70. With this arrangement, pulling on steering wire 70 causes deflection of the distal region toward the

steering wire side, as indicated by the curved, dashed arrow in FIG. 24. Enhanced deflection may be achieved by the techniques described previously, such as weakening of the steering wire side or stiffening of the opposite side of flexible tube 88 within bending region 68. The primary advantage of this embodiment is that by bonding hollow tube 86 to guide core 190, a substantially incompressible column support is created along the length of flexible body 64, close to the axis of steering wire 70, where maximum compression occurs. Thus, substantially less compression of flexible body 64 and less unwanted movement of the distal region occurs during tensioning of steering wire 70.

A further embodiment is disclosed in FIGS. 27 through 29. This embodiment is closely analogous to that disclosed in FIGS. 15 through 18, with the principal difference being that steering wire 70 is used as a push-wire instead of a pull-wire. Flexible tube 88 has a lumen 96 for steering wire 70 and a second lumen 90 for coaxial actuating assembly 170, as best seen in FIG. 28. An optional central lumen 124 may be included for reasons described previously. Restraining layer 194 is surroundingly disposed upon flexible body 88 throughout its full length, except in bending region 68 where it is only disposed on one side, as best seen in FIG. 29. Restraining layer 194 is preferably fabricated from a material that is laterally flexible but which is substantially more resistant to stretching than the material used to fabricate flexible tube 88. Appropriate materials include polyester (such as Mylar, trademark of E.I DuPont Co.), polyamide (such as Kapton, trademark of E.I DuPont Co.), polycarbonate, nylon or cellophane. Restraining layer 194 may also be formed from the same classes of polymers suggested previously for fabricating flexible tube 88, but formulated for reduced elasticity. Restraining layer 194 may be a separate element which is bonded or heat-shrunk to flexible tube 88, or it may be a layer of extruded material having properties different from those of the tubular structure of flexible tube 88. Alternatively, a virtual restraining layer 194 may be formed by a surface treatment applied to flexible tube 88 to produce a thin zone of material having decreased elasticity. By way of example, gas plasma polymerization (Advanced Surface Technology, Inc., Billerica, MA) can produce a surface with increased cross-linking and thus reduced elasticity. A further option is to form restraining layer 194 from a coating process.

With this arrangement, pushing on steering wire 70 causes flexible body 64 to be placed in tension. The only portion of flexible tube 88 that is unrestrained is the steering wire side of bending region 68. Thus, as the steering wire side stretches in response to the applied tension, bending region 68 deflects toward the opposite side, as indicated by the curved, dashed arrow in FIG. 27. Little unwanted movement of the distal region occurs since the main length of flexible body 64 is restrained from stretching. It will be appreciated that restraining layer 194 may alternatively be comprised of an array of restraining filaments, and that restraining layer 194 may be disposed within the wall of flexible tube 88.

A different embodiment is disclosed in FIGS. 30 through 32 wherein hollow tube 86 functions as both an element of coaxial actuating assembly 170 and as the steering control means. Coaxial actuating assembly 170 is slidably disposed within a lumen of flexible body 88. Friction between hollow tube 86 and flexible tube 88 may be reduced by methods previously described herein for similar sliding elements. This embodiment includes torsional-stiffening layer 198 disposed around flexible tube 88 except in bending region 68, as seen in FIGS. 30 and 31. It will be appreciated that this embodiment need not incorporate torsional-stiffening layer 198 to provide the intended deflection properties. Restraining filaments 200 are disposed in a radially-symmetrical manner about and in parallel with the long axis of flexible tube 88. In the bending region, however, restraining filaments 200 are only disposed along one side of flexible tube 88, as best seen in FIGS. 30 and 32. Outer coating 196 may be any appropriate medical-grade sealant or resin that secures torsional-stiffening layer 198 and restraining filaments 200 to flexible tube 88 while imparting desired properties such as flexibility and lubricity to flexible body 64. Control assembly 130 (not shown), as previously described, is configured to impart a sliding movement to control wire 84 relative to hollow tube 86 for purposes of actuating the movable effector elements. In the present embodiment, control assembly 130 is also configured to independently impart a pushing force to hollow tube 86 relative to flexible tube 88. By pushing on hollow tube 86, flexible body 64 is placed in tension. Restraining filaments 200 prevent all portions of flexible body 64 from stretching in response to the applied tension except one side of

bending region 68. As a result, bending region 68 deflects away from the unrestrained side, as indicated in FIG. 30. Restraining filaments 200 may optionally be attached to jaw support 72 and to an analogous structure in control assembly 130 if the bond between the filaments and flexible body 88 is not adequate. Further, instead of restraining filaments 200, a restraining layer may be disposed within or upon flexible tube 88 in a manner similar to that described for the embodiment of FIG. 27.

Yet another embodiment is disclosed in FIGS. 33 through 35. As in previous embodiments, this embodiment incorporates a side-pull effector mechanism. Coaxial actuating assembly 170 is disposed within lumen 90 of flexible tube 88, as best seen in FIG. 34. Similarly, steering wire 70 is disposed within lumen 96 of flexible tube 88. However, unlike previous embodiments, steering wire 70 is surrounded by incompressible hollow tube 202 along the full length of flexible body 64 except in bending region 68. Hollow tube 202 is bonded to lumen 96 with a resilient adhesive such as silicone or polyurethane having a high shear strength. With this arrangement, pulling or pushing on steering wire 70 causes deflection of bending region 68 toward or away from, respectively, the steering wire side. Hollow tube 202 prevents compression or stretching of the main length of flexible body 64, thereby eliminating unwanted movement of the distal region during deflection. The primary advantage of this approach is the bilateral deflection of bending region 68. However, the added expense of hollow tube 202 is a distinct disadvantage. It will be appreciated that flexible tube 88 may have a single, large lumen through which coaxial actuating assembly 170, hollow tube 202 and steering wire 70 may be disposed. In such an embodiment, an anchoring element would need to be attached inside the lumen at the proximal edge of bending region 68 to couple hollow tube 202 to at least one of hollow tube 86 or flexible tube 88.

The embodiment illustrated in FIG. 33 incorporates, by way of example only, an elastomeric sealing diaphragm 214 in the distal region. Diaphragm 214 is a flat disc-shaped element preferably made from a resilient elastomer such as silicone. A tiny hole in the center of diaphragm 214 tightly surrounds control wire 84, preventing contaminating fluids from entering

the inner regions of flexible body 64. Numerous sealing alternatives are conceivable in place of diaphragm 214, including molded packings, sealing boots and plugs. By preventing contaminating fluids from reaching the inner regions of flexible body 64, the device is made easier to clean and safer to re-use.

FIG. 36 illustrates one embodiment of control assembly 130 including a deflection actuation means. Finger spools 134 and 136 are slidably disposed along control shaft 138. Two thumb rings, 132a and 132b, are disposed at the proximal end of control assembly 130. Flexible body 64 is fixedly anchored in interface region 156 of control shaft 138. Cross-bar 140, extending through finger spool 134 and through forked elements 148a and 148b (not visible), is linked to the effector control wire. Cross-bar 142, extending through finger spool 136 and through forked elements 206a and 206b (not visible), is linked to the steering control means. By sliding finger spool 134 toward or away from thumb rings 132a and 132b, cross-bar 140 pulls or pushes, respectively, on the effector control wire. Likewise, by sliding finger spool 136 toward or away from thumb rings 132a and 132b, cross-bar 142 pulls or pushes, respectively, on the steering control means. Thus, by using the thumb and fingers of one hand, the operator can control operation of the effector assembly; while with the thumb and fingers of the other hand, the operator can simultaneously control the amount of deflection of the bending region.

An embodiment directed at improving the utility of control assembly 130 is presented in FIG. 37. As in the previous embodiment, finger spool 134 is slidably disposed upon control shaft 138 so as to pull or push on the effector control wire. However, instead of a finger spool for deflection control, this embodiment employs collar 144. Fingertip dimples 210 are disposed radially around collar 144 to aid in gripping collar 144. As collar 144 is rotated, an internal cross-bar pushes or pulls on the steering control means, causing deflection of flexible body 64.

FIG. 38 shows an enlarged, sectional view of a detailed embodiment of the control assembly presented in FIG. 37. The proximal end of flexible body 64 is fixedly disposed within the distal end of interface region 156, using adhesive bonding or the like. Proximal anchor 162,

which may be formed from metal such as brass, is attached to the bore of interface region 156 by press-fitting, adhesive bonding or the like. Hollow tube 86 is fixedly anchored to proximal anchor 162 by means such as welding, brazing, soldering, adhesive bonding or the like. An aperture in proximal anchor 162 allows slidable passage of steering wire 70. It will be appreciated that proximal anchor 162 may be eliminated by incorporating an analogous anchoring region for hollow tube 86 directly into interface region 156. Hollow tube 86 extends beyond proximal anchor 162 to be slidably received by the lumen of outer sleeve 150, as can be seen in FIG. 40. Referring to FIG. 38, finger spool 134 is slidably disposed along control shaft 138. Cross-bar 140 extends across the center of finger spool 134 and is guided and restrained by forked elements 148a and 148b, as shown in FIGS. 38 and 39. Cross-bar 140, preferably fabricated from metal such as brass, has a blind, internally-threaded bore on one end to receive set screw 146. A transverse hole in the center of cross-bar 140 is located at the end of the threaded bore. Outer sleeve 150 enshrouds control wire 84 and the proximal end of hollow tube 86. Outer sleeve 150 is disposed into the transverse hole of cross-bar 140 such that advancement of set screw 146 will secure outer sleeve 150 and control wire 84 within the transverse hole. Outer sleeve 150 is preferably fabricated from metal tubing such as stainless steel, having an outer diameter on the order of .03 inches and a wall thickness of about .006 inches. As best seen in FIG. 40, a central bore through control shaft 156 slidably receives the distal end of outer sleeve 150, allowing free longitudinal movement of outer sleeve 150 within the bore, but relatively little lateral movement. The length of outer sleeve 150 is chosen such that at the proximal-most position of finger spool 134, hollow tube 86 remains within the lumen of outer sleeve 150. Likewise, at the distal-most position of finger spool 134, proximal anchor 162 is positioned so as not to impede distal movement of outer sleeve 150. With this configuration, control wire 84 is always surrounded by a tubular element, thereby preventing any deformative buckling that could occur when cross-bar 140 pushes on control wire 84.

Rotating collar 144 has a roughly cylindrical shape, as best seen in FIGS. 38 and 41. Along the central portion of the inside surface of collar 144 is disposed annular groove 208, sized to slidably capture cross-bar 152. Along the distal portion of the inside surface of collar 144 are

disposed a set of continuous female threads 158. Female threads 158 are sized to mate with segments of male threading 160 which are disposed upon the outer surfaces of forked elements 206a (not shown) and 206b, as can be seen in FIG. 42. Referring to FIG. 38, cross-bar 152 is guided and restrained by forked elements 206a (not shown) and 206b. Cross-bar 152, preferably fabricated from metal such as brass, has a blind, internally-threaded bore on one end to receive set screw 154. A transverse hole in the center of cross-bar 152 is located at the end of the threaded bore. Steering wire 70 is disposed into the transverse hole of cross-bar 152 such that advancement of set screw 154 will secure steering wire 70 within the transverse hole. A second transverse hole in cross-bar 152 allows free passage of hollow tube 86. As collar 144 is rotated, it advances along its threads either distally or proximally, forcing cross-bar 152 to moved distally or proximally, respectively. In this manner, rotation of collar 144 causes pushing or pulling on steering wire 70, thereby causing deflection of flexible body 64. It will be appreciated that a tubular constraint similar to outer sleeve 150 may be disposed around the unconstrained length of steering wire 70 to prevent buckling, if necessary.

FIG. 43 shows an enlarged, sectional view of an alternate embodiment of the control assembly presented in FIG. 37. This embodiment is configured to be compatible with the deflection mechanism illustrated in FIG. 30, wherein hollow tube 86 comprises the steering control means. The structure is similar to that illustrated in FIG. 38, except that proximal anchor 162 and steering wire 70 are eliminated and cross-bar 152 is simplified. Finger spool 134, cross-bar 140 and related elements function in the same manner as in the previously-described embodiment. The proximal end of flexible body 64 is fixedly anchored in the bore of interface region 156 using adhesive bonding or the like, as best seen in FIG. 44. Hollow tube 86 extends beyond the proximal end of flexible body 64, through cross-bar 152 and into the lumen of outer sleeve 150. Referring to FIG. 43, hollow tube 86 is fixedly attached within hole 216 of cross-bar 152 by means of soldering, brazing, welding, adhesive bonding or the like. With this arrangement, rotation of collar 144 causes cross-bar 152 to move distally or proximally, applying a pushing or pulling force, respectively, to hollow tube 76 relative to flexible tube 88. Consequently, such

rotation of collar 144 results in deflection of bending region 68. As can be seen, this configuration results in a simpler control assembly. Optionally, torsional-stiffening layer 198 or restraining filaments 200 (see FIG. 30) may be brought out from flexible body 64 and fixedly anchored within interface region 156.

The embodiment depicted in FIG. 43 is shown with molded packings 164a and 164b disposed between the inner surface of finger spool 134 and the outer surface of control shaft 138. Similarly, molded packings 166a and 166b are disposed between the inner surfaces of collar 144 and the outer surfaces of control shaft 138 and interface region 156, respectively. These packings form a seal to prevent contaminating fluids from reaching the inner regions of control assembly 130 and flexible body 64. Many effective sealing alternatives are readily conceivable, including diaphragms, sealing boots, plugs and the like, or combinations thereof. By preventing contaminating fluids from reaching such inner regions, the device is easier to clean and safer to re-use.

It will be apparent that the presentation of control assembly embodiments herein is not intended to be exhaustive. Other improvements and modifications will be readily conceivable to those skilled in the art. For example, the control assembly depicted in FIGS. 37 through 44 may be adapted for one-handed operation by replacing finger dimples 210 with fins extending radially outward from rotating collar 144. Turning of rotating collar 144 could be accomplished by pushing on such fins with a finger from the same hand that grasps finger spool 134 and thumb ring 132. Additionally, a scissor-type actuating arrangement is readily conceivable as a replacement for finger spool 134 and thumb ring 132. Further, it is also apparent that instead of torquing flexible body 64 by rotation of the entire control assembly 130, an active mechanism may be included that turns the proximal end of flexible body 64 in response to a pulling, pushing or twisting movement of a separate control member.

A forceps device incorporating a seal at both the distal end and proximal end protects the

inner regions of flexible body 64 from infiltration by fluids. However, such a fully-sealed device presents several problems. First, initial sterilization of the device by the manufacturer becomes more difficult. For example, if using a sterilizing agent such as ETO gas (ethylene oxide), the gas must be able to penetrate all areas of the device, and must likewise be vented from such areas before use on a patient. A tight seal at both ends of the device inhibits penetration of the gas into the inner regions. Second, disinfection using a process that requires an elevated temperature or pressure creates a pressure difference between the inner and outer regions of a completely sealed device. For embodiments having significant volumes of trapped air within the inner regions, this pressure difference can result in damage to the device.

A solution to the initial sterilization problem is to perform the sterilization step prior to the sealing of the inner regions, followed by final assembly in a sterile environment. Alternatively, a vent hole may be added to allow the passage of sterilizing gases into the inner regions. The vent hole would need to be sealed prior to removal of the device from the sterile environment. These approaches, however, do not solve the potential pressure difference problem. By adding a hydrophobic barrier to the vent hole, gases can pass into the inner regions but contaminating fluids cannot. Such a hydrophobic barrier may be fabricated from a microporous membrane such as woven nylon or polyester available from Performance Systematix, Inc. (Caledonia, MI). Alternatively, the vent may be fitted with a valve means that can be activated manually or in response to a physical change such as temperature or pressure. Another solution is to employ a hydrophobic plug sealing means at either or both ends of the device, or to use a microporous membrane diaphragm.

From the foregoing, it will be appreciated that the present invention provides a flexible forceps device with improvements in accordance with the above-described objects. While particular embodiments of the invention have been described, it is not intended that the invention be limited exactly thereto, as it is intended that the invention be as broad in scope as the art will permit. Thus, while a particular flexible forceps device for retrieving biopsy samples is disclosed, it will be appreciated that other types of flexible forceps instruments, such as graspers, dissectors,

scissors and the like would be equally as appropriate applications for the improvements encompassing the present invention. Likewise, while the invention is disclosed for use with medical endoscopes, it is equally well-suited for use with industrial borescopes. Also, while various materials are described as being preferred for various parts, it will be appreciated that other materials could be utilized. Therefore, it will be apparent to those skilled in the art that other changes and modifications may be made to the invention as described in the specification without departing from the spirit and scope of the invention as so claimed.

Although this invention has been disclosed and illustrated with reference to particular embodiments, the principles involved are susceptible for use in numerous other embodiments which will be apparent to persons skilled in the art. The invention is, therefore, to be limited only as indicated by the scope of the appended claims.

_C_L_A_I_M_S_

What is claimed is:

1. A flexible forceps device comprising:

an elongated, flexible body with a nominally straight neutral axis having a distal end and a proximal end;

an effector assembly attached to said distal end of said flexible body, said effector assembly consisting of at least one movable element linked to a rigid support piece;

a control assembly attached to the proximal end of said flexible body, said control assembly including an effector controller and a deflection controller;

wherein actuation of said effector controller causes said at least one movable element to move relative to said rigid support piece, and

wherein actuation of said deflection controller causes at least a portion of said flexible body to arcuately bend away from said nominally straight neutral axis.

2. In a flexible forceps device according to claim 1 wherein said actuation of said effector controller means causes relatively little movement of said flexible body.

3. In a flexible forceps device according to claim 1 wherein said flexible body has a specific bending zone.

4. In a flexible forceps device according to claim 3 wherein actuation of said deflection controller causes relatively little contraction or extension of said flexible body, except in said bending zone.

5. In a flexible forceps device according to claim 1 further comprising a torsional-stiffening means disposed upon or within said flexible body.

6. In a flexible forceps device according to claim 1 wherein said flexible body and said effector assembly may be slidably inserted through a channel of an endoscope and operated therethrough.

7. In a flexible forceps device according to claim 6 wherein said at least one movable element comprises a pair of jaws.

8. In a flexible forceps device according to claim 7 wherein said rigid support piece is configured to provide a hinge means for said jaws.

9. In a flexible forceps device according to claim 7 wherein said jaws are biopsy forceps jaws.

10. In a flexible forceps device according to claim 1 wherein said flexible, elongated body is a length of extruded pliant material.

11. In a flexible forceps device according to claim 1 wherein said flexible body is a spring-coil.

12. In a flexible forceps device according to claim 10 further comprising a seal near at least one of said proximal end or said distal end of said flexible body to prevent fluids from reaching the inner regions of said flexible body.

13. A flexible forceps device comprising:

an elongated, flexible body having a nominally straight neutral axis and having at least one lumen extending therethrough;

a coaxial actuating assembly extending through a lumen of said flexible body, said coaxial actuating assembly consisting of:

a flexible, hollow tube having a distal end and a proximal end with a lumen extending

therethrough defining a long axis, said flexible, hollow tube being substantially incompressible along said long axis, and

an effector control wire extending through said lumen of said flexible, hollow tube, said effector control wire having a distal end and a proximal end;

an effector assembly having at least one movable element, said effector assembly disposed at said distal end of said flexible body, said at least one movable element linked to said distal end of said effector control wire;

a deflection control means extending at least partially through a lumen of said flexible body, said deflection control means fixedly attached to at least one of said distal end of said flexible body or said effector assembly;

a control assembly attached to the proximal end of said flexible body, said control assembly including an effector controller and a deflection controller;

said effector controller configured to slidably move said control wire through said lumen of said flexible, hollow tube, wherein slidable movement of said control wire through said lumen of said flexible, hollow tube results in movement of said at least one movable element;

said deflection controller configured to push and pull said deflection actuation means relative to said flexible body,

wherein said pushing and pulling of said deflection actuation means results in arcuate deflection of at least a portion of said flexible body relative to said nominally straight neutral axis.

14. In a flexible forceps device according to claim 13 wherein said flexible body has a designated bending zone.

15. In a flexible forceps device according to claim 14 wherein the geometrical properties of said flexible body are different in said designated bending zone relative to the rest of said flexible body.

16. In a flexible forceps device according to claim 14 wherein the material properties

of said flexible body are different in said designated bending zone relative to the rest of said flexible body.

17. In a flexible forceps device according to claim 13 further comprising a torsional-stiffening means disposed upon or within said flexible body.

18. In a flexible forceps device according to claim 13 wherein said coaxial actuating assembly is offset from the central long axis of said flexible body.

19. In a flexible forceps device according to claim 13 wherein said deflection actuation means is a wire.

20. In a flexible forceps device according to claim 13 wherein said deflection actuation means is a cord.

21. In a flexible forceps device according to claim 13 wherein said deflection actuation means is fixedly attached to said effector assembly.

22. In a flexible forceps device according to claim 13 wherein said deflection actuation means is pivotally attached to said effector assembly.

23. In a flexible forceps device according to claim 18 wherein said effector assembly includes a lever, said lever linked to both said effector control wire and said at least one movable element.

24. In a flexible forceps device according to claim 13 wherein said hollow tube also functions as said deflection actuation means.

25. In a flexible forceps device according to claim 13, said effector controller including

a first thumb ring and first sliding spool, and said deflection controller including a second thumb ring and second sliding spool.

26. In combination for use in a cavity in a patient,

first means constructed to extend through the cavity in the patient,

an effector operable in different relationships,

second means operatively coupled to the effector and the first means for selectively providing an operation of the effector in individual ones of the different relationships while the first means is in the cavity in the patient, and

third means operatively coupled to the effector for steering the effector laterally in the cavity in the patient in a direction transverse to the progressive positions in the cavity and in substantially isolated relationship to the operation of the effector by the second means.

27. In a combination as set forth in claim 26,

the first means being constructed to extend through the cavity in the patient in the direction of the progressive positions in the cavity,

the third means being displaced laterally from the second means in the direction transverse to the directions of the progressive positions in the cavity to isolate the steering by the third means relative to the operation of the effector by the second means.

28. In a combination as set forth in claim 26,

a flexible non-bendable body extending from the first means and having proximal and distal ends,

a bendable body having a proximal end attached to the flexible non-bendable body at the distal end of the flexible non-bendable body and extending from the distal end of the flexible body, the bendable body having a distal end,

the second means having proximal and distal ends and being operatively coupled at the proximal end to the distal end of the bendable body and being operatively coupled at the distal end to the effector for selectively providing the operation of the effector in the individual ones of

the different relationships.

29. In a combination as set forth in claim 28,

the third means being operative to pivot the bendable body relative to the flexible non-bendable body to steer the effector in the cavity in the patient in the direction transverse to the direction of the progressive positions in the cavity.

30. In a combination as set forth in claim 26,

the effector constituting forceps operable in open and closed relationship respectively corresponding to first and second ones of the different relationships.

31. In a combination as set forth in claim 26,

fourth means for providing a torsional stiffening of the flexible non-bendable body to provide for a rotation of the flexible body to a desired position in the cavity without any torsional displacement of the flexible non-bendable body.

32. In a combination as set forth in claim 28,

the first means being constructed to extend through the cavity in the patient in the direction of the progressive positions in the cavity,

the third means being displaced from the second means in the direction transverse to the direction of the progressive positions in the cavity to isolate the steering by the third means from the operation of the effector by the second means, and

fourth means for providing a torsional stiffening of the flexible non-bendable body to provide for a rotation of the flexible non-bendable body to a desired position without any torsional displacement of the flexible non-bendable body.

33. In combination for use in a cavity in a patient,

a body constructed to extend longitudinally through the cavity in the patient,

an effector assembly having different operative relationships,

first means operatively coupled at opposite ends to the body and the effector assembly for selectively operating the effector assembly in individual ones of the different operative relationships, and

second means operatively coupled to the body and the effector assembly for steering the effector assembly in the cavity in the patient in a direction transverse to the direction of the progressive positions in the cavity,

the first and second means being operative on the effector assembly in substantially isolated relationship to each other in the direction transverse to the direction of the progressive positions in the cavity.

34. In a combination as set forth in claim 33,

third means disposed at a position external to the cavity in the patient for providing a controlled operation of the first means in obtaining the selective operation of the effector assembly in the individual ones of the different operative relationships, and

fourth means disposed at a position external to the cavity in the patient for providing a controlled operation of the second means in steering the effector assembly in the cavity in the patient in the direction transverse to the direction of the progressive positions in the cavity.

35. In a combination as set forth in claim 33,

the effector assembly being opened in a first one of the different operative relationship and being closed in a second one of the different operative relationships.

36. In a combination as set forth in claim 34,

the third means being movable to obtain the selective operation of the effector assembly in the individual ones of the different operative relationships, and

the fourth means being movable to obtain the steering of the effector assembly in the cavity in the patient in the direction transverse to the direction of the progressive positions in the cavity in the patient.

37. In a combination as set forth in claim 36,

the third means being movable in the direction of the progressive positions in the cavity in the patient to obtain the selective operation of the effector assembly in the individual ones of the different operative relationships, and

the fourth means being rotatable to obtain the steering of the effector assembly in the cavity in the patient in the direction transverse to the direction of the progressive positions in the cavity in the patient.

38. In a combination as set forth in claim 36,

the third means being movable in the direction of the progressive positions in the cavity to obtain the selective operation of the effector assembly in the individual ones of the different operative relationships, and

the fourth means being movable in the direction of the progressive positions in the cavity to obtain the steering of the effector assembly in the cavity in the patient in the direction transverse to the direction of the progressive positions in the cavity in the patient.

39. In a combination as set forth in claim 33,

the first means being disposed for movement in the cavity in the patient in the direction of the progressive positions in the cavity, and

the second means being displaced from the first means in a direction transverse to the direction of the progressive positions in the cavity for steering the effector assembly in the direction transverse to the direction of the progressive positions in the cavity without affecting the position of the first means in the direction of the progressive positions in the cavity.

40. In a combination as set forth in claim 33,

third means for providing for a rotation of the effector assembly to any desired position in the direction transverse to the direction of the progressive positions in the cavity without substantially any change in the torsional position of the effector assembly relative to the second

means and the third means.

41. In a combination as set forth in claim 36,

the fourth means being operable to bend the body in accordance with the movement of the fourth means relative to the body,

the effector assembly being opened in first one of the different operative relationships and being closed in a second one of the different operative relationships.

42. In a combination as set forth in claim 38,

the fourth means being operable to position the effector assembly in the direction transverse to the direction of the progressive positions in the cavity in the patient in accordance with the rotation of the effector assembly, and

the effector assembly being opened in a first one of the different operative relationships and being closed in a second one of the different operative relationships.

43. In a combination as set forth in claim 42,

the first means being disposed for movement in the direction of the progressive positions in the cavity in the patient,

the second means being displaced from the first means in the transverse direction relative to the direction of the progressive positions in the cavity in the patient for steering the body in the direction transverse to the cavity without affecting the position of the first means in the direction of the progressive positions in the cavity, and

fifth means for providing for a rotation of the effector assembly to any desired position in the cavity around the periphery of the cavity without substantially any change in the torsional position of the effector assembly relative to the second means and the third means.

44. In combination for use in a cavity in a patient,

a hollow flexible body constructed to extend through the cavity in the direction of the

progressive positions in the cavity in the patient,

an effector assembly having different operative relationships,

first means including a control wire extending through the hollow flexible body and selectively actuatable for providing a selective operation of the effector assembly in individual ones of the different operative relationships in accordance with the selective actuation of the control wire, and

second means including a steering wire extending through the hollow flexible body and selectively actuatable for steering the effector assembly to different positions in the cavity in the patient in a direction transverse to the direction of the progressive positions in the cavity in the patient in accordance with the selective actuation of the steering wire,

the selective operation of the effector assembly by the first means and the selective steering of the effector assembly by the second means being in substantially isolated relationship to each other.

45. In a combination as set forth in claim 44,

linkage means operatively coupled to the control wire in a first relationship for providing the selective operation of the effector assembly in the individual ones of the different operative relationships in accordance with the selective actuation of the control wire, and

the second means including the linkage means operatively coupled to the steering wire in a relationship different from the different operative relationships for providing the selective steering of the effector assembly to the different positions in the cavity in the patient in the direction transverse to the direction of the progressive positions in the cavity in the patient.

46. In a combination as set forth in claim 44,

the first means being operative to selectively actuate the control wire to provide the selective operation of the effector assembly in the individual ones of the different operative relationships in accordance with such selective actuation of the control wire, and

the second means being operative to actuate the steering wire to provide the steering of the effector assembly to the different transverse positions in the cavity in the patient in accordance

with such selective actuation of the steering wire.

47. In a combination as set forth in claim 44,

means for holding the control wire and the steering wire to provide for a simultaneous movement of the control wire and the steering wire through the cavity in the direction of the progressive positions in the cavity in the patient.

48. In a combination as set forth in claim 44,

the first means and the second means being displaced from each other in the cavity in the direction transverse to the direction of the progressive positions in the cavity to provide for an operation of each of the first and second means independently of the operation of the other one of the first and second means without any substantially effect on the operation of the other one of the first and second means.

49. In a combination as set forth in claim 44,

the second means being constructed to steer the steering wire in the direction transverse to the direction of the progressive positions in the cavity in accordance with the actuation of the steering wire.

50. In a combination as set forth in claim 45,

the first means including the linkage means being operatively coupled to the control wire in a first relationship for providing the selective operation of the effector assembly in the individual ones of the different operative relationships,

the second means including the linkage means and being operatively coupled to the steering wire in a second relationship for providing the steering of the effector assembly to the different positions in the cavity in the patient in a direction transverse to the direction of the progressive positions in the cavity,

means for holding the control wire and the steering wire to provide for a movement of the control wire and the steering wire simultaneously through progressive positions in the cavity, and

the effector assembly having open and closed positions.

51. In combination for use in a cavity in a patient,

a hollow bendable tube disposed in the cavity in the patient,

an effector assembly having different operative relationships,

linkage means operatively coupled to the effector assembly for operating the effector assembly in individual ones of the different operative relationships,

first means disposed in the hollow bendable tube and operatively coupled to the linkage means for obtaining the operation of the effector assembly in a first one of the different relationships in accordance with an actuation of the first means in a first direction and for obtaining the operation of the effector assembly in a second one of the different relationships in accordance with an actuation of the first means in a second direction opposite to the first direction,

second means operatively coupled to the linkage means for obtaining the bending of the hollow tube, in a direction transverse to the direction of the progressive positions in the cavity in the patient, in substantially isolated relationship to the operation of the effector assembly by the first means.

52. In a combination as set forth in claim 51,

the first means being operatively coupled to the linkage means at a first position in the linkage means to obtain the operation of the effector assembly in the individual ones of the different operative relationships in accordance with the actuation of the first means,

the second means being operatively coupled to the linkage means at a second position displaced from the first position to obtain the bending of the hollow tube in the direction transverse to the direction of the progressive positions in the cavity in the patient.

53. In a combination as set forth in claim 50,

the first means including a control wire operatively coupled to the linkage means to actuate the linkage means in accordance with the actuation of the first means, and

the second means including a steering wire operatively coupled to the linkage means to bend the hollow flexible tube in accordance with the actuation of the second means.

54. In a combination as set forth in claim 50,

the first means including third means for operating upon the linkage means in a first relationship to obtain the operation of the effector assembly in the individual ones of the different operative relationships, and

the second means including fourth means for operating upon the linkage means in a second relationship different from the first relationship to obtain the bending of the hollow bendable tube.

55. In a combination as set forth in claim 54,

the third means being movable in first and second opposite directions relative to the hollow bendable tube for operating upon the linkage means to obtain the operation of the effector assembly in the individual ones of the different operative relationships in accordance with the direction of movement of the third means relative to the hollow bendable tube,

the fourth means being movable in the first and second opposite directions relative to the hollow bendable tube for operating upon the linkage means to obtain the bending of the hollow bendable tube.

56. In a combination as set forth in claim 54,

fifth means for providing for a rotation of the effector assembly without substantially any torsional displacement of the effector assembly during such rotational movement.

57. In a combination as set forth in claim 53,

the first means being disposed relative to the second means to isolate the operation of the first means on the linkage means from the operation of the second means on the linkage means.

58. In a combination as set forth in claim 55,

the control wire being movable relative to the hollow bendable tube for operating upon the linkage means to obtain the operation of the effector assembly in the individual ones of the different operative relationships in accordance with the direction of movement of the control wire

relative to the hollow bendable tube,

the steering wire being movable relative to the hollow bendable tube for operating upon the linkage means to obtain the bending of the hollow bendable tube in the direction transverse to the direction of the progressive positions in the cavity in the patient.

59. In a combination as set forth in claim 58,

fifth means for providing for a rotation of the effector assembly without substantially any torsional movement of the effector assembly during such rotational movement, and

the first means being disposed relative to the second means in the direction transverse to the direction of the progressive positions in the cavity in the patient to isolate the operation of the first means on the linkage means from the operation of the second means on the linkage means.

60. In combination for use in a cavity in a patient,

a hollow flexible body extending through the cavity,

an effector assembly having different operative relationships,

first means disposed in the flexible hollow body for selectively operating upon the effector assembly to obtain the

operation of the effector assembly selectively in the different relationships, and

second means disposed in the flexible hollow body in displaced relationship to the first means in a direction transverse to the direction of the progressive positions in the cavity for operating upon the flexible hollow tube to steer the effector assembly to a particular position in the cavity without substantially affecting the operation of the first means on the effector assembly.

61. In a combination as set forth in claim 60,

the flexible hollow body being constructed to steer the flexible hollow body in a direction transverse to the direction of the progressive positions in the cavity in the patient in accordance with the operation of the second means.

62. In a combination as set forth in claim 60,

the flexible hollow body being notched on one peripheral side of the flexible hollow body at progressive positions along at least a portion of the flexible hollow body to steer the flexible hollow body to the particular position

in the cavity in accordance with the operation of the second means.

63. In a combination as set forth in claim 60,

third means associated with the flexible hollow body for directing the steering of the flexible hollow body by the second means in a particular direction transverse to the direction of the progressive positions in the cavity.

64. In a combination as set forth in claim 63,

the third means including a helical spring disposed on the flexible hollow body and having first turns disposed close together at positions relatively removed from the effector assembly and having second turns spaced further apart than the first turns at positions relatively close to the effector assembly,

the first means and the second means being disposed within the third means.

65. In a combination as set forth in claim 63,

the third means including a restraining layer disposed on the flexible hollow body at progressive positions on the flexible hollow tube.

66. In a combination as set forth in claim 63,

the third means including a torsional-stiffening layer disposed substantially completely around the flexible hollow body at positions relatively removed from the effector assembly and including a layer disposed partially around the flexible hollow body at positions relatively close to the flexible hollow body.

67. In a combination as set forth in claim 63,

the third means including restraining filaments disposed partially around the flexible hollow body in spaced relationship to one another at positions relatively close to the effector assembly and extending in the direction of the progressive positions in the cavity and disposed substantially completely around the flexible hollow body at positions relatively removed from the effector assembly and extending in the direction of the progressive positions in the cavity.

68. In a combination as set forth in claim 60,

means disposed around the periphery of the flexible hollow body for providing for the rotation of the flexible hollow tube while providing torsional stiffness to the flexible hollow body.

69. In a combination as recited in claim 60,

the flexible hollow body and the second means being disposed relative to each other to obtain the operation of the effector assembly in the different operative relationships and steering of the effector assembly independently of each other.

70. In combination for use in a cavity in a patient,

an effector assembly having different operative relationships,

a hollow body having flexible non-bendable properties at positions relatively removed from the effector assembly and having flexible bendable properties at positions relatively close to the effector assembly, the hollow body being constructed to extend through the cavity in the patient,

first means extending through the hollow body and operatively coupled to the effector assembly for selectively operating the effector assembly in individual ones of the different operative relationships, and

second means extending through the hollow body and operatively coupled to the effector assembly for providing a controlled bending of the bendable portion of the hollow body, in substantially isolated relationship to the operation of the first means on the effector assembly, to move the effector assembly to any desired position in the cavity.

71. In a combination as set forth in claim 70,

third means disposed at the end of the hollow body removed from the effector assembly and operatively coupled to the first means for obtaining a selective operation of the effector assembly by the first means in the individual ones of the different operative relationships, and

fourth means disposed at the end of the hollow body removed from the effector assembly and operatively coupled to the second means for obtaining the controlled bending of the bendable portion of the flexible hollow body by the second means.

72. In a combination as recited in claim 70,

the bendable portion of the hollow body being constructed to bend in a particular direction upon the operation of the second means in providing the controlled bending of the bendable portion of the hollow body.

73. In a combination as recited in claim 70,

third means associated with the bendable portion of the hollow body for directing the bending of the bendable portion of the hollow body in a particular direction upon the operation of the second means in providing the controlled bending of the bendable portion of the hollow body.

74. In a combination as set forth in claim 72,

third means disposed at the end of the hollow body removed from the effector assembly and operatively coupled to the first means for obtaining a selective operation of the effector assembly by the first means in the individual ones of the different operative relationships, and

fourth means disposed at the end of the hollow body removed from the effector assembly and operatively coupled to the second means for obtaining the controlled bending of the bendable portion of the hollow body by the second means,

the effector assembly including forceps open in a first individual one of the different operative relationships and closed in a second individual one of the different operative relationship.

75. In a combination as set forth in claim 74,

third means disposed on the hollow body near the end of the hollow body removed from the effector assembly for operating upon the first means to obtain the selective operation by the first means of the effector assembly in the individual ones of the different operative relationships, and

fourth means disposed on the hollow body near the end of the hollow body removed from the effector assembly for operating upon the second means to obtain the controlled bending of the hollow body by the second means.

76. In a combination as set forth in claim 75,

the third means and the fourth means being disposed externally of the cavity in the patient.

77. In a combination as set forth in claim 72,

third means associated with the hollow body for obtaining a bending of the hollow body in the particular direction in accordance with the operation of the second means.

78. In a combination as set forth in claim 72,

linkage means operatively coupled to the effector assembly for operating the effector assembly in the individual ones of the different operative relationships,

fifth means disposed in the hollow body at a position removed from the linkage means for restricting the movements of the first means and the second means relative to the hollow body at positions further removed from the linkage means than the fifth means.

79. In a combination as set forth in claim 75,

the hollow body being substantially incompressible at positions removed from the linkage means.

80. In a combination as set forth in claim 33,

means for sealing the first means relative to the body.

81. In a combination as set forth in claim 35,

fifth means for sealing the body relative to an individual one of the third means and the fourth means.

82. In a combination as set forth in claim 44,

third means for sealing the control wire relative to the first means.

83. In a combination as set forth in claim 74,

fifth means for sealing the first means relative to the third means, and

sixth means for sealing the second means relative to the fourth means.

84. In a combination as set forth in claim 82,

the third means and the fourth means being disposed externally of the cavity in the patient.

85. In a combination as set forth in claim 74,

the third means including fifth means movable in the direction of the progressive positions in the cavity to obtain the selective operation of the effector assembly by the first means in the first and second operative relationships, and

the fourth means including sixth means movable in the direction of the progressive positions in the cavity to obtain the controlled bending of the bendable portion of the hollow tube by the second means.

86. In a combination as set forth in claim 74,

the third means including fifth means movable in the direction of the progressive positions

in the cavity to obtain the selective operation of the effector assembly by the first means in the first and second operative relationships, and

the fourth means including sixth means rotational to obtain the controlled bending of the bendable portion of the hollow tube by the second means.

87. In combination for use in a cavity in a patient, the cavity having a wall,

a hollow body non-bendable in a first portion and bendable in a second portion displaced from the first portion, the hollow body having a lumen,

a hollow tube extending through the lumen in the hollow body, the hollow tube having a lumen,

a control wire extending through the lumen in the hollow tube,

an effector having different operative relationships, the effector being operatively coupled to the control wire for actuation to the different relationships in accordance with the movements of the control wire in the direction of the progressive positions in the cavity,

first means coupled to the hollow body for moving the control wire to the positions providing the different operative relationships of the effector,

second means for bending the flexible portion of the hollow body to move the effector against the wall of the cavity without affecting the operation of the first means on the effector.

88. In a combination as set forth in claim 87,

the hollow body being constructed to bend in a particular direction, and

third means disposed on the hollow body for providing a rotation of the hollow body without any torsional displacement of the hollow body.

89. In a combination as set forth in claim 87,

third means for sealing the control wire relative to the hollow body.

90. In a combination as set forth in claim 87,

third means for sealing the hollow body relative to the first means, and

fourth means for sealing the hollow body relative to the second means.

91. In a combination as set forth in claim 87,

a control shaft,

the first means being disposed on the control shaft and being movable relative to the control shaft and coupled to the hollow body for moving the control wire to the positions of the different operative relationships of the effector,

the second means being disposed on the control shaft and being movable relative to the control shaft for bending the flexible portion of the body to move the effector against the wall of the cavity.

92. In a combination as set forth in claim 91,

the hollow body being constructed to bend in a particular direction, and

third means disposed on the hollow body for providing a rotation of the hollow body without any torsional displacement of the hollow body.

93. In a combination as set forth in claim 87,

the lumen in the hollow body constituting a first lumen,

the hollow body having a second lumen displaced from the first lumen in a direction transverse to the direction of the progressive positions in the cavity in the patient,

a steering wire extending through the second lumen in the hollow body and operatively coupled to the effector for bending the flexible portion of the hollow body to move the effector against the wall of the cavity, and

the second means being operatively coupled to the steering wire for operating upon the steering wire to bend the flexible portion of the hollow body to move the effector against the wall of the cavity without substantially affecting the operation of the first means on the effector.

94. In a combination as set forth in claim 93,

a control shaft,

the first means being disposed on the control shaft and being movable in the direction of the progressive positions in the cavity on the control shaft and coupled to the hollow body for moving the control wire to the positions of the different operative relationships of the effector, and

the second means being disposed on the control shaft and being movable on the control shaft in the direction of the progressive positions in the cavity and coupled to the steering wire for operating upon the steering wire to bend the flexible portion of the hollow body to move the effector against the wall of the cavity without substantially affecting the operation of the first means on the effector.

95. In a combination as set forth in claim 93,

a control shaft,

the first means being disposed on the control shaft and being movable on the control shaft in the direction of the progressive positions in the cavity and coupled to the hollow body for moving the control wire to the positions of the different operative relationships of the effector, and

the second means being disposed on the control shaft and being movable on the control shaft in the direction of the progressive positions in the cavity and coupled to the steering wire for operating upon the steering wire to bend the flexible portion of the hollow body to move the effector against the wall of the cavity without substantially affecting the operation of the first means on the effector.

96. In a combination as set forth in claim 51,

the linkage means including a first link having first and second ends, the first means being operatively coupled to the first link near the first end of the first link and the second means being operatively coupled to the first link near the second end of the first link, and

the linkage means including second links operatively coupled to the first link at a position intermediate the positions of the operative coupling of the first and second means to the first link and operatively coupled to the effector assembly to provide the effector assembly with the individual ones of the different operative relationships.

97. In a combination as set forth in claim 96,

fifth means for providing for a rotation of the effector assembly without substantially any torsional movement of the effector assembly during such rotational movement, and

the first means being disposed relative to the second means in the direction transverse to the direction of the progressive positions in the cavity in the patient to isolate the operation of the first means on the first link from the operation of the second means on the first link.

98. In a combination as set forth in claim 78,

the linkage means including a first link, the first means being operatively coupled to the first link near the first end of the first link and the second means being operatively coupled to the second link near the second end of the first link, and

the linkage means including second links operatively coupled to the first link at a position intermediate the positions of the operative coupling of the first and second means to the first link and operatively coupled to the

effector assembly to provide the effector assembly with the individual ones of the different operative relationships.

99. In a combination as set forth in claim 98,

fifth means for providing for a rotation of the effector assembly without substantially any torsional movement of the effector assembly during such rotational movement, and

the first means being disposed relative to the second means in the direction transverse to the direction of the progressive positions in the cavity in the patient to isolate the operation of the first means on the first link from the operation of the second means on the first link.

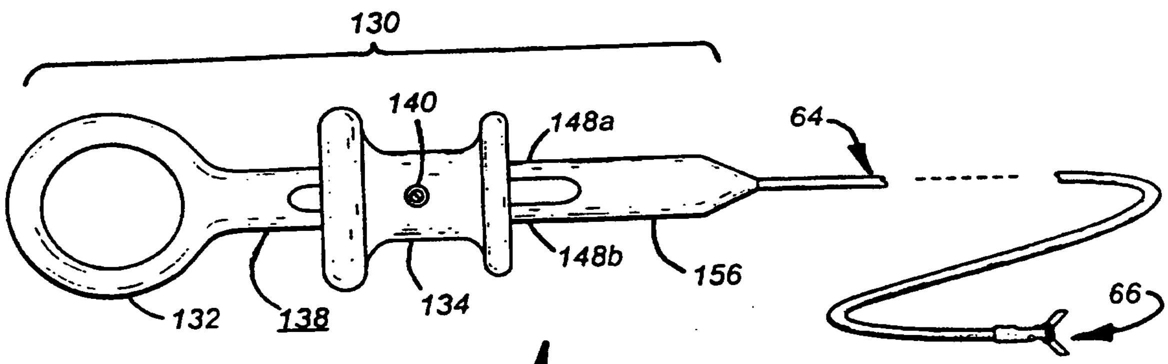


FIG. 1

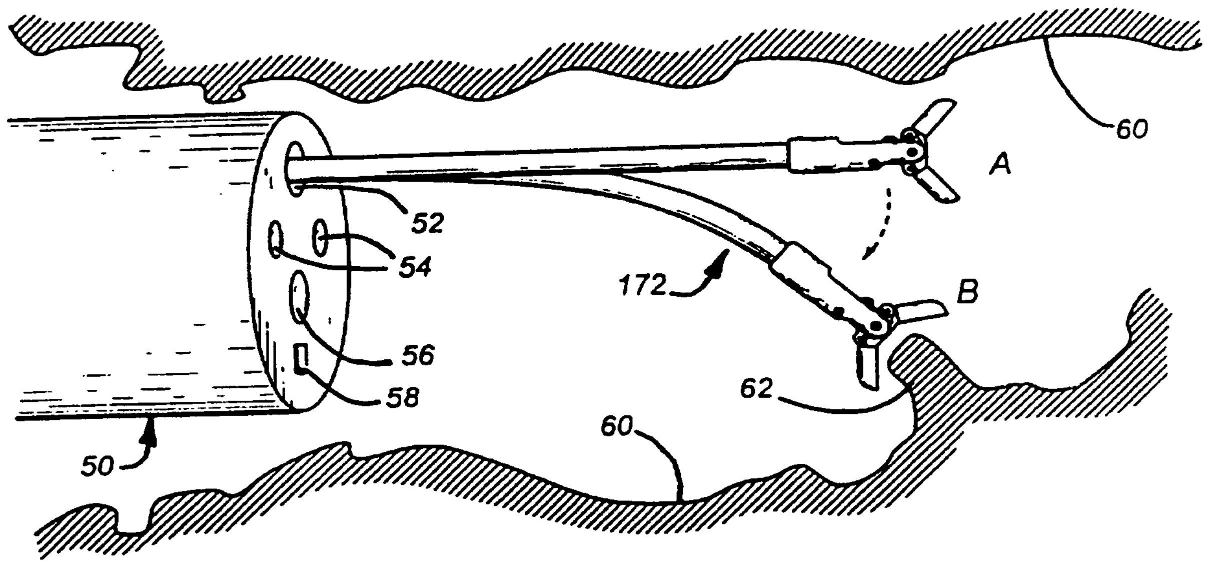


FIG. 2

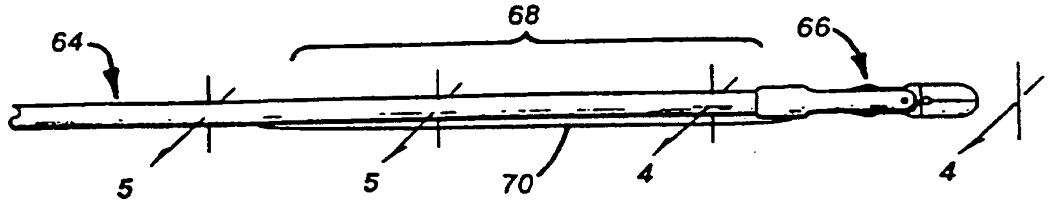
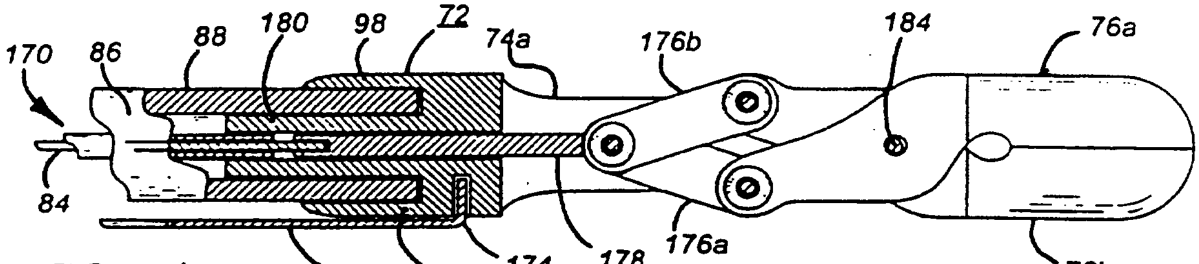


FIG. 3



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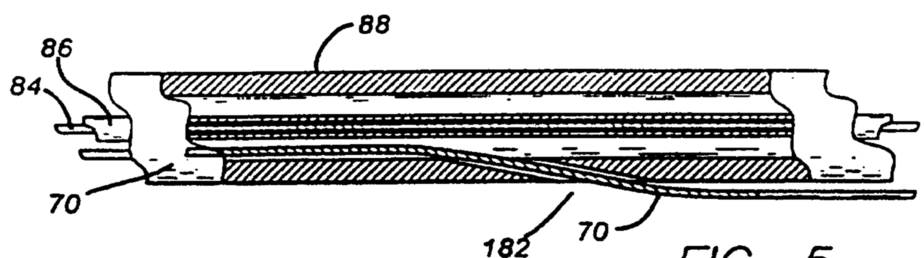


FIG. 5

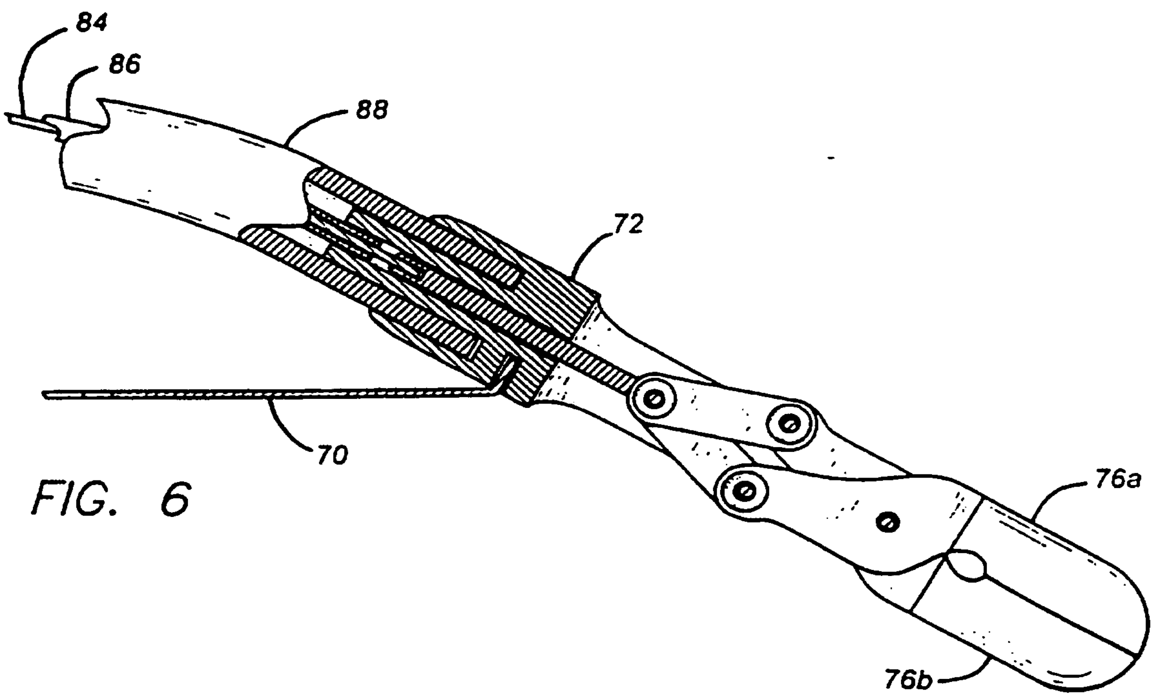
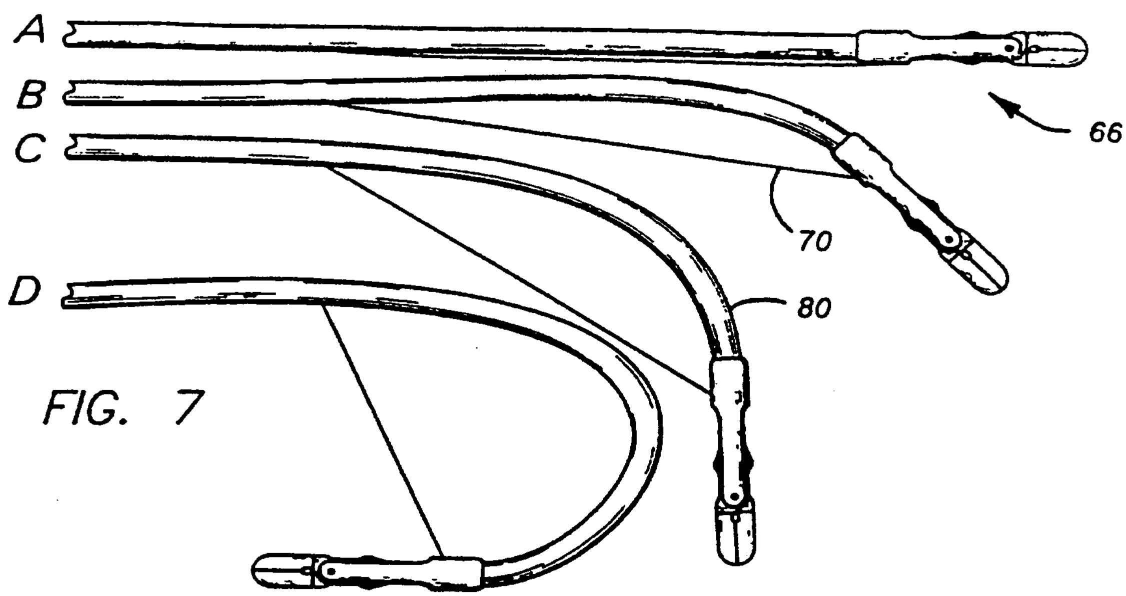


FIG. 6



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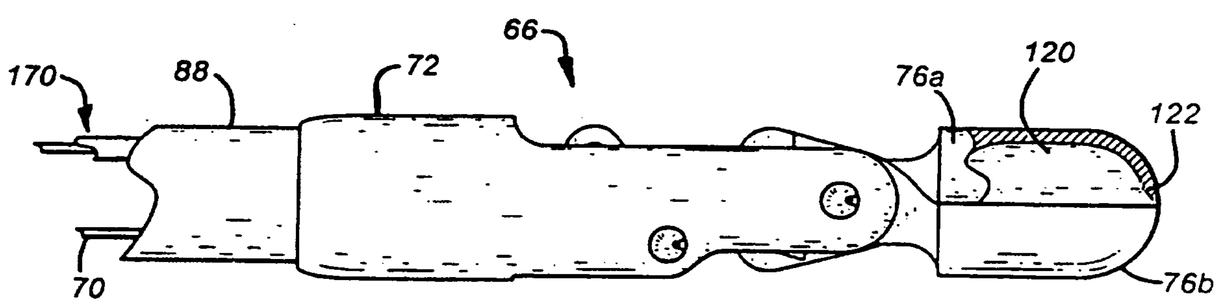

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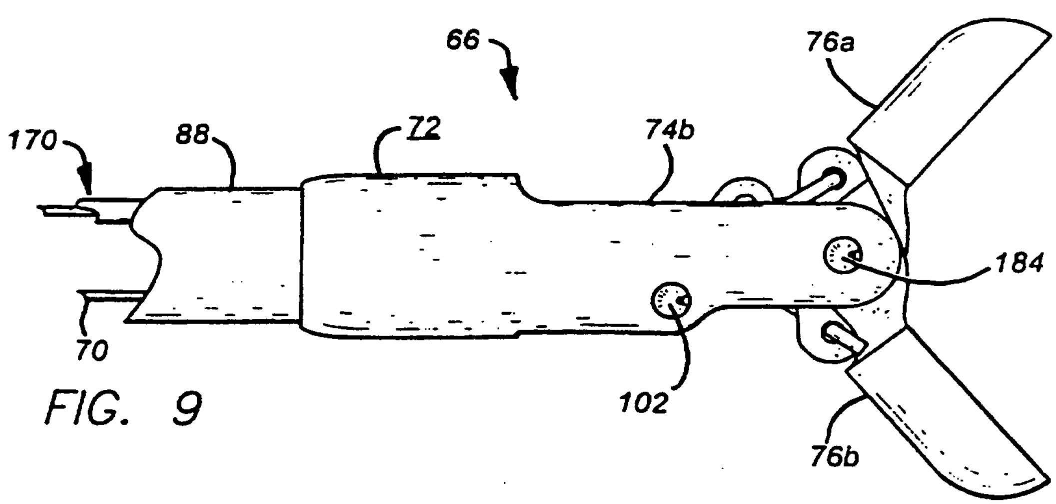
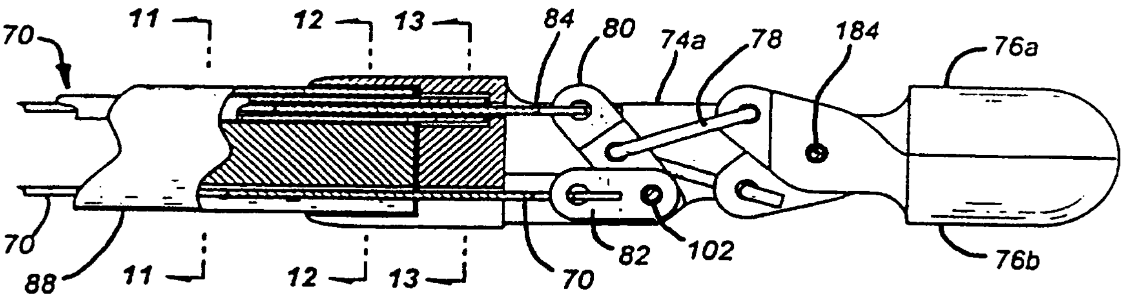


FIG. 9

FIG. 10



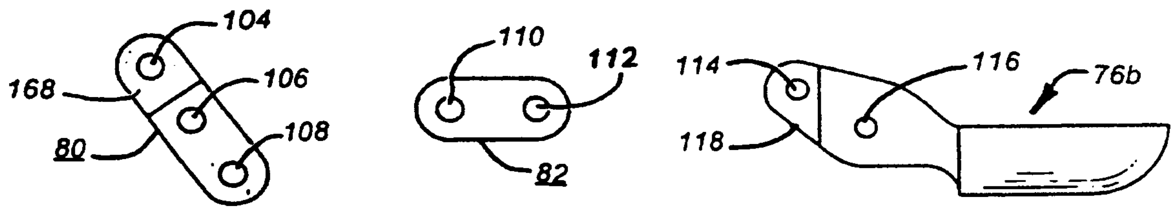
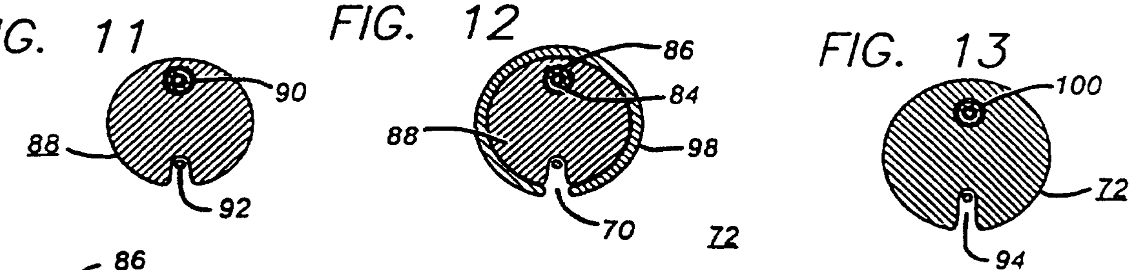


FIG. 10A FIG. 10B FIG. 10C

FIG. 11 FIG. 12 FIG. 13



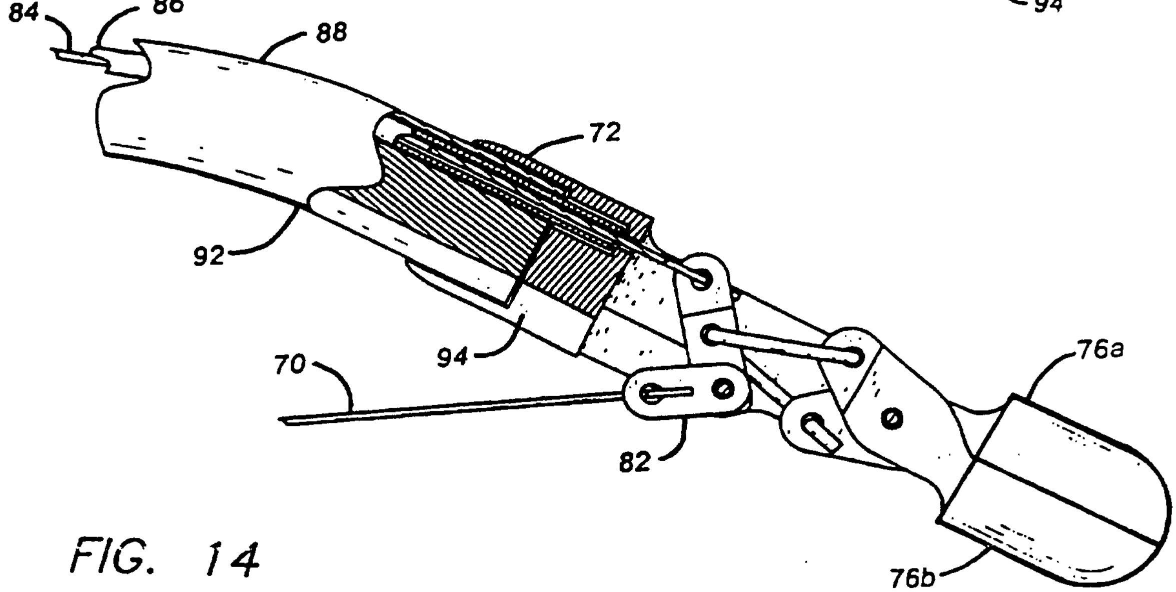
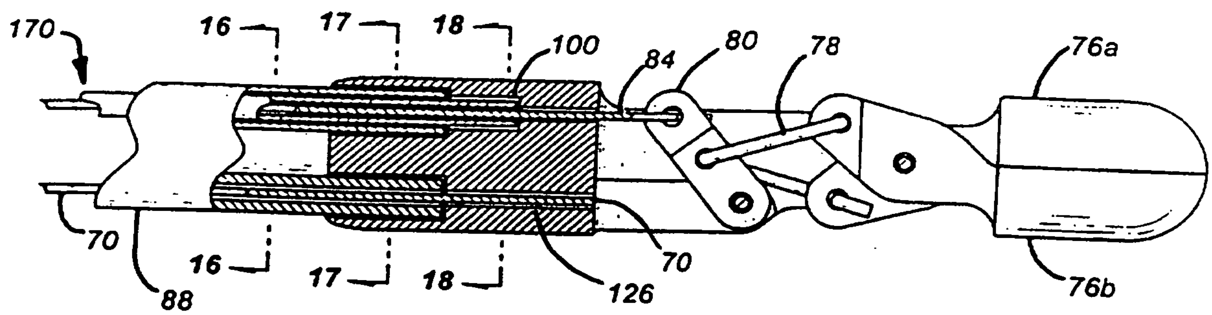


FIG. 14

FIG. 15



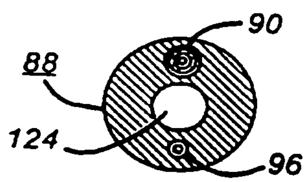


FIG. 16

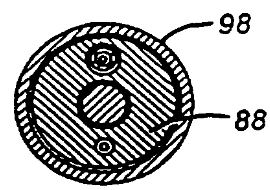


FIG. 17

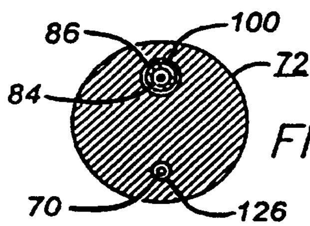
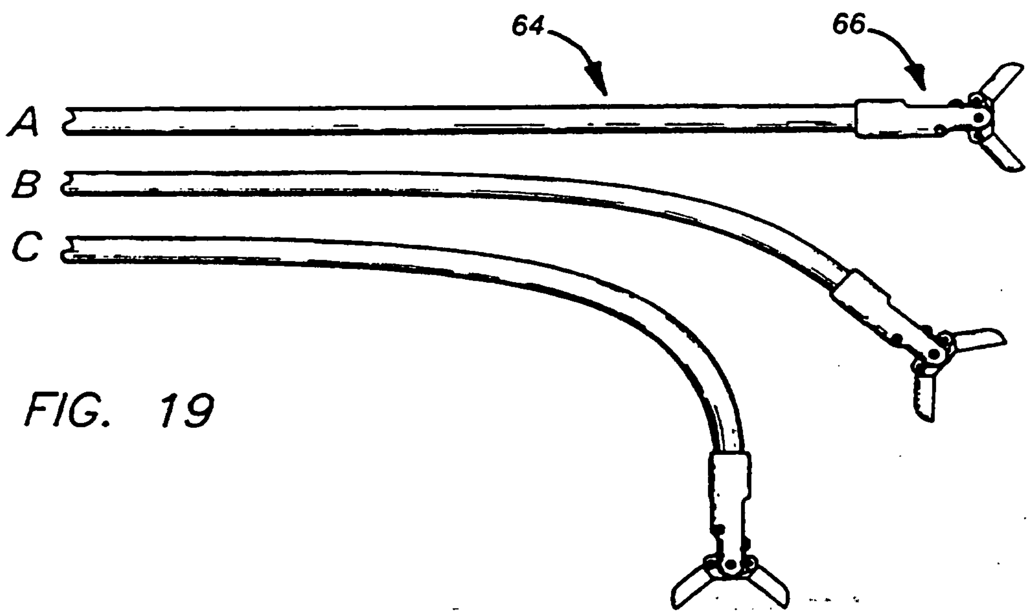


FIG. 18



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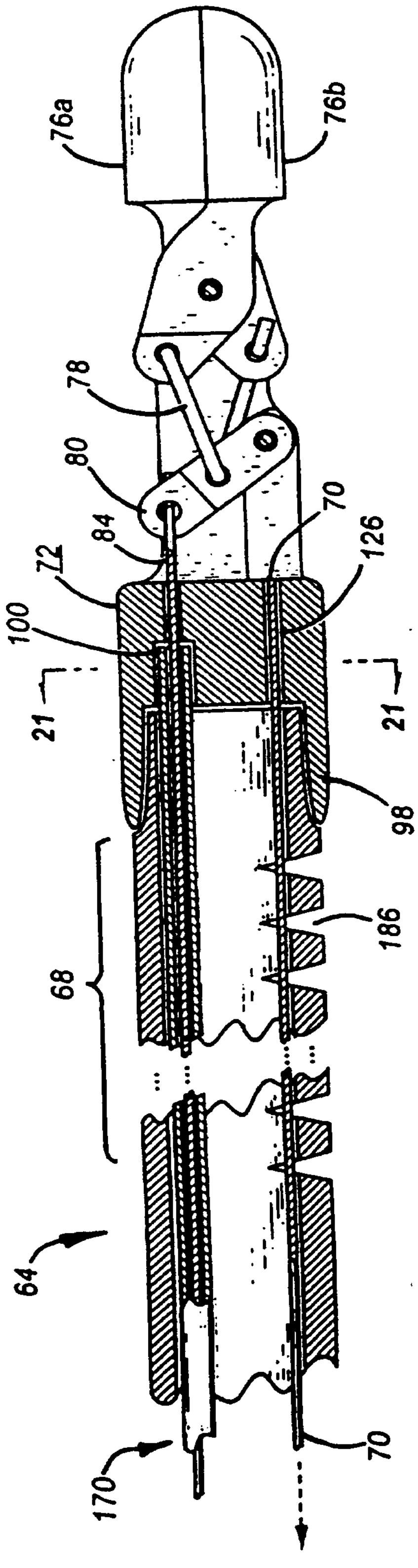

FIG. 20A

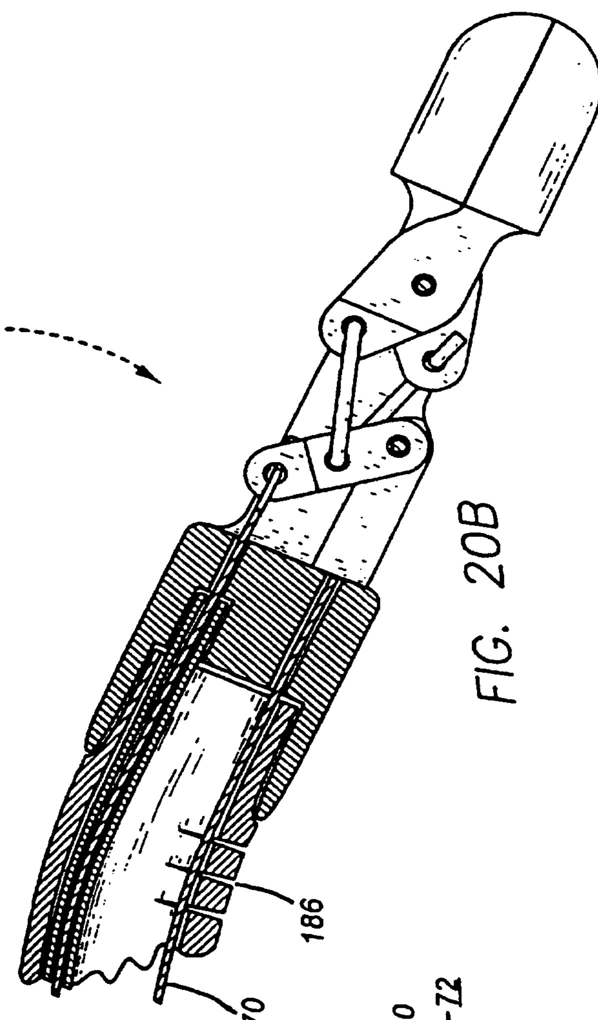

FIG. 20B

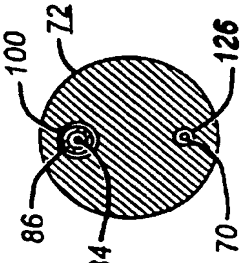

FIG. 21

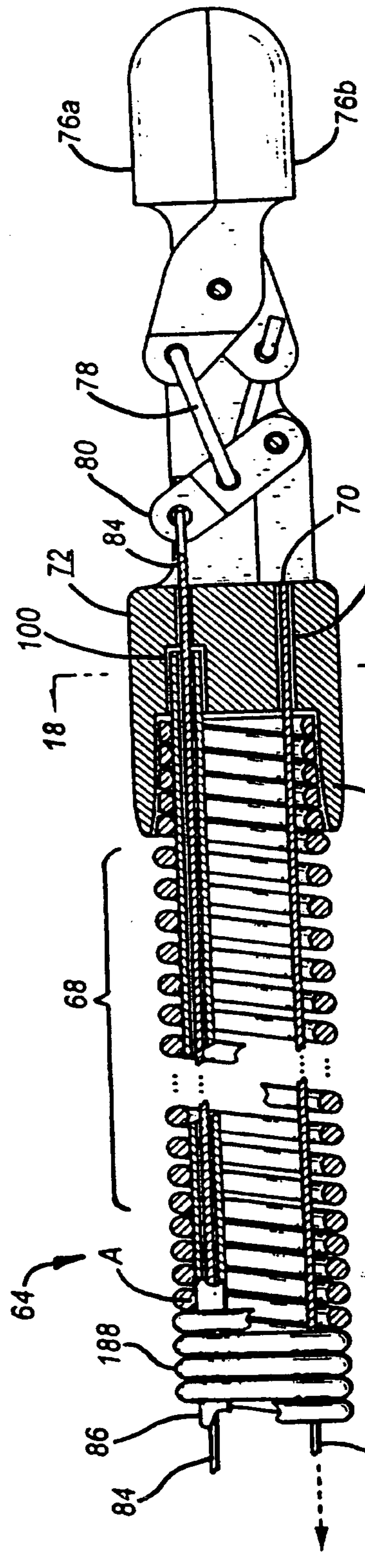

FIG. 22A

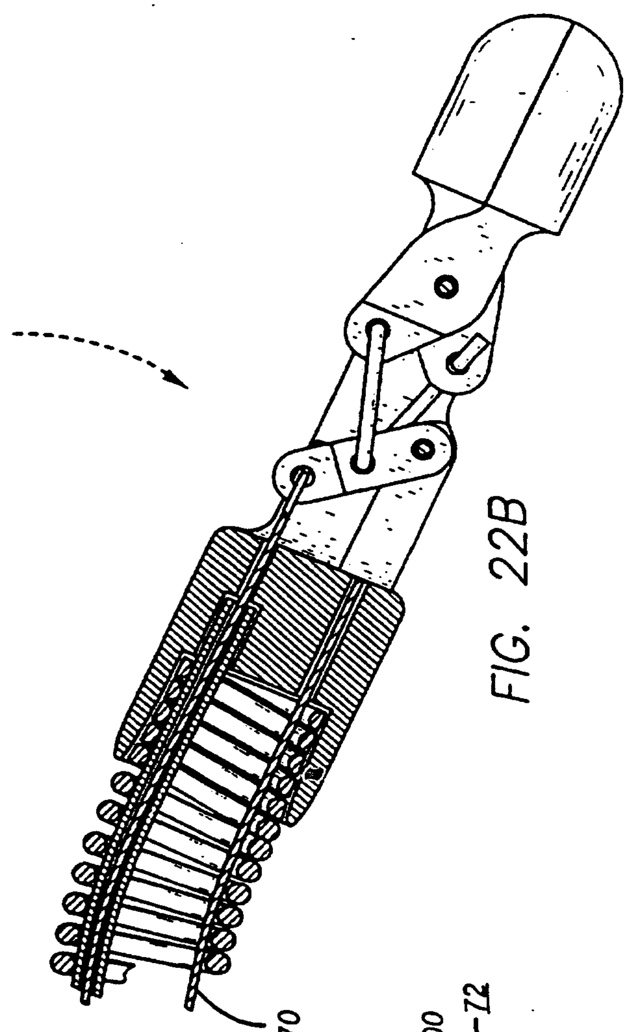

FIG. 22B

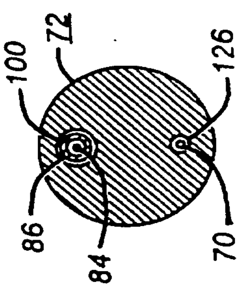

FIG. 23

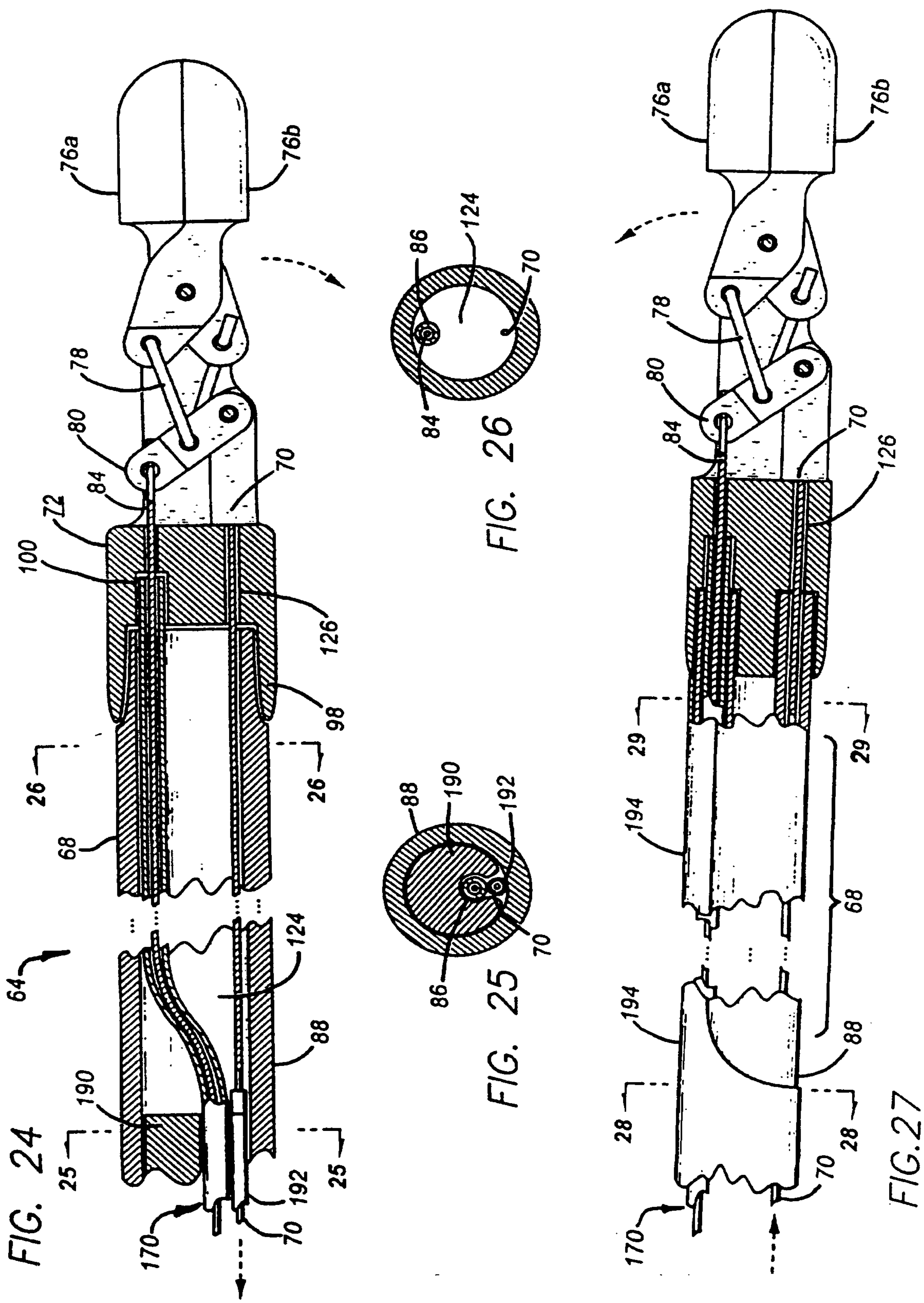

FIG. 24

FIG. 25

FIG. 26

FIG. 27

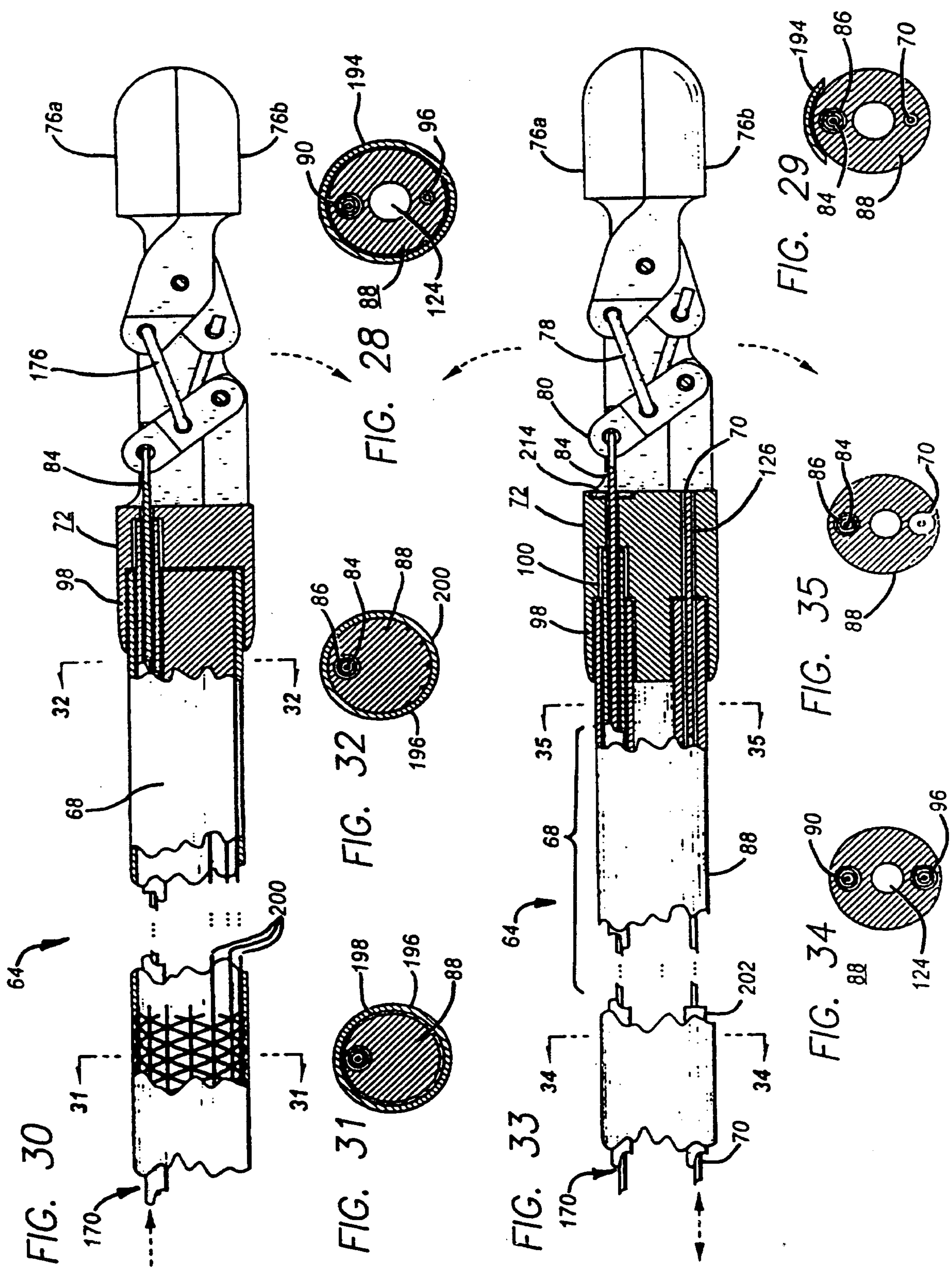

FIG. 28

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FIG. 35

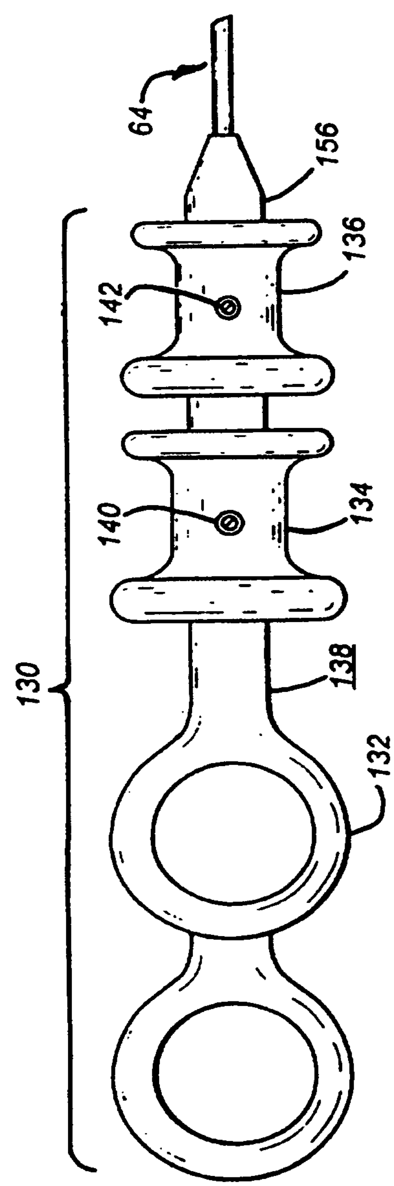
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FIG. 36

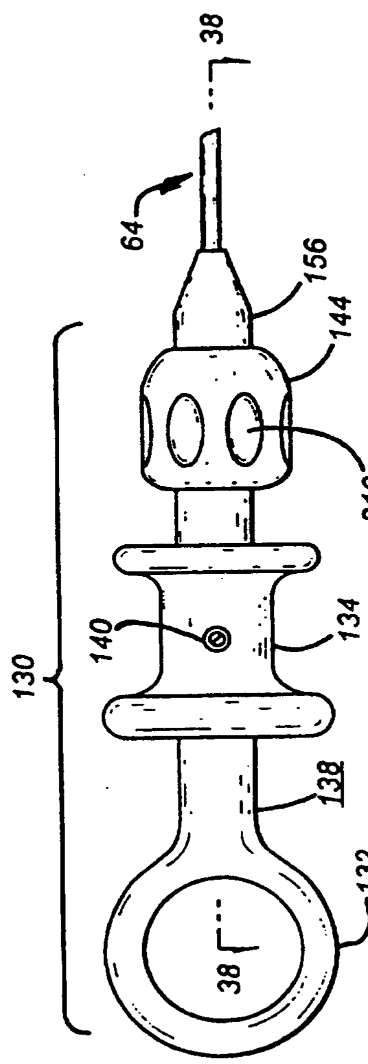
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FIG. 37

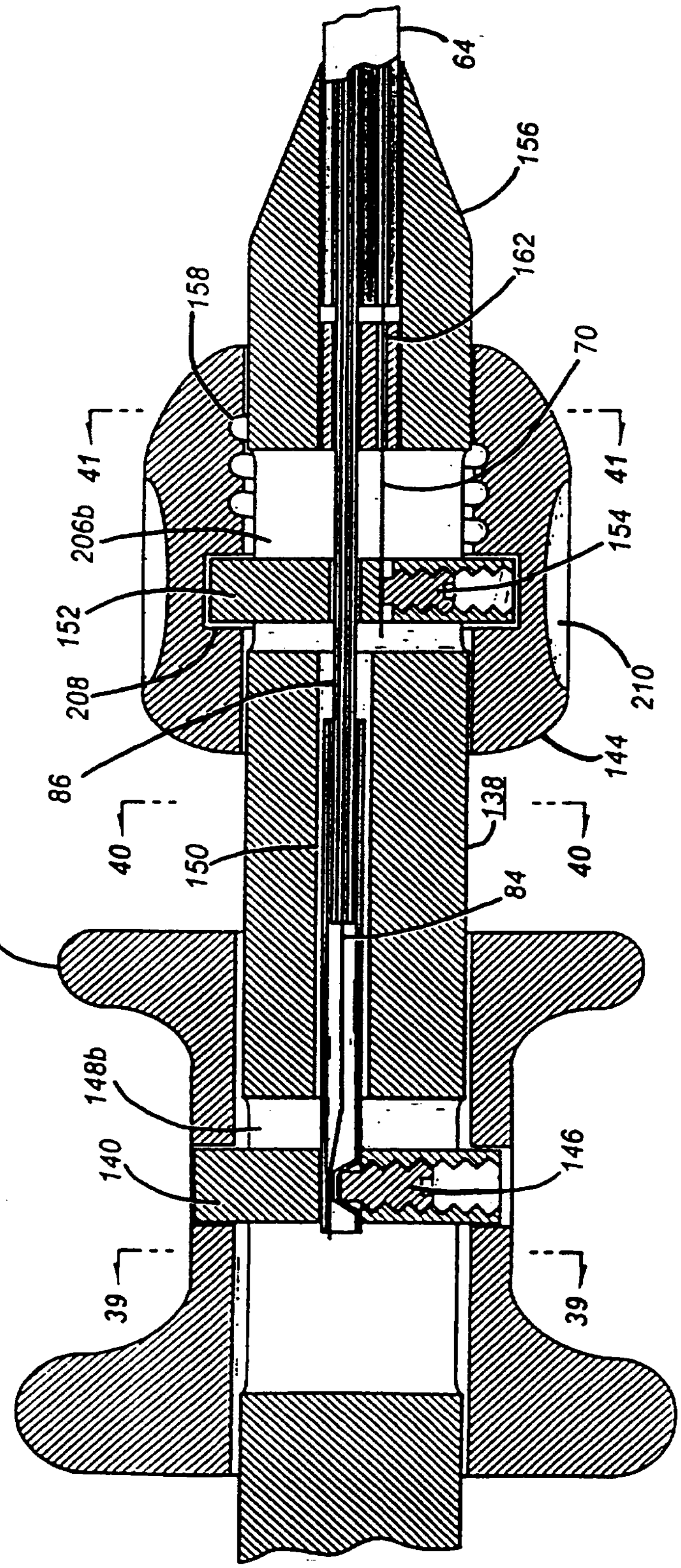

FIG. 38

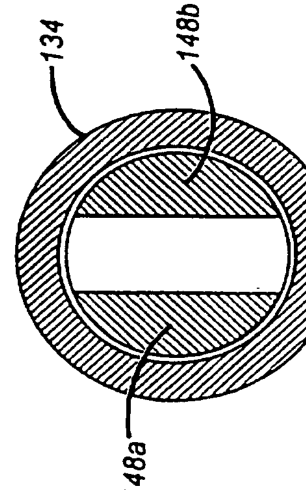

FIG. 39

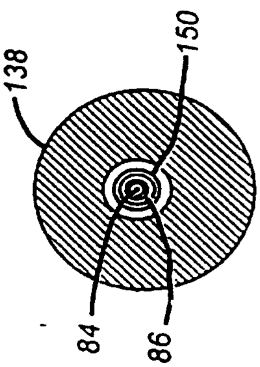

FIG. 40

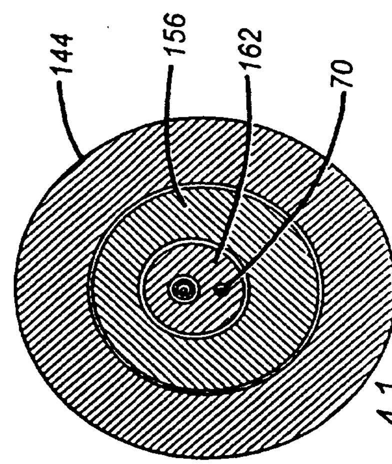

FIG. 41

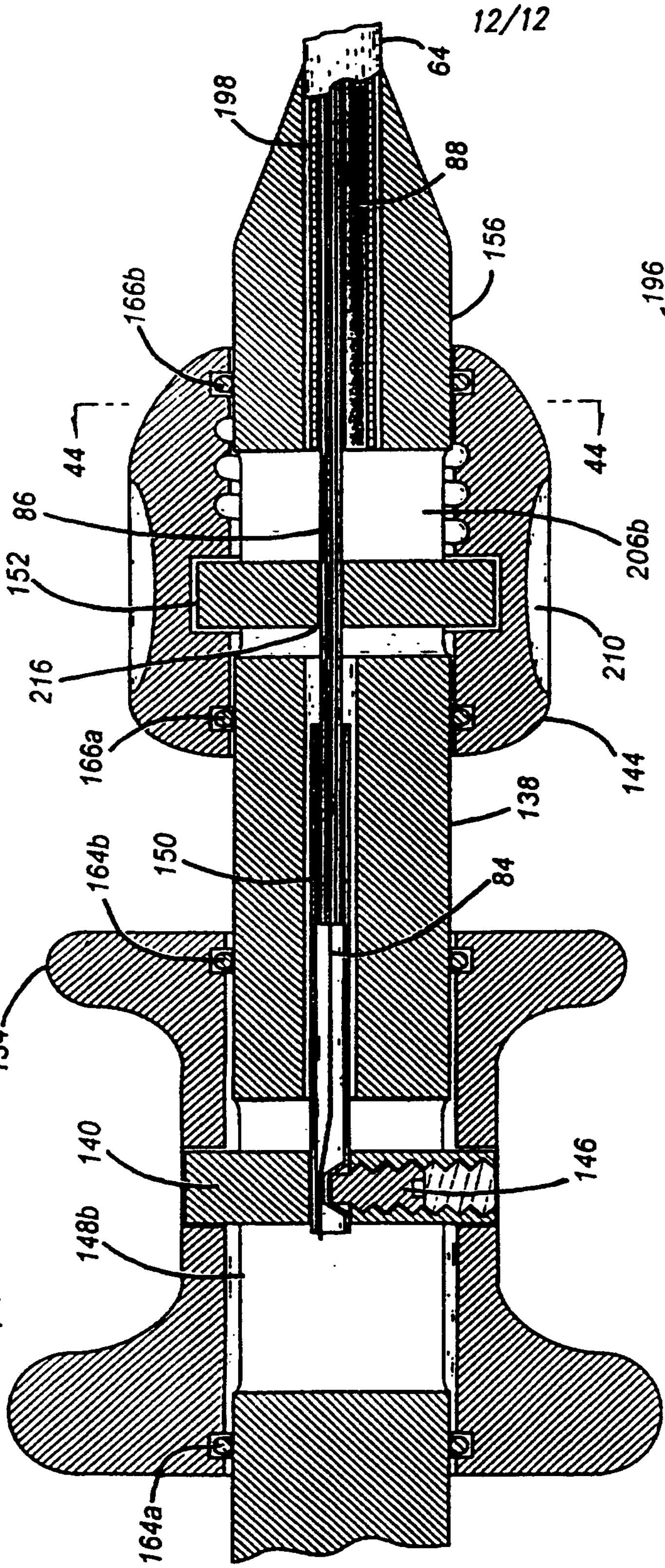

FIG. 43

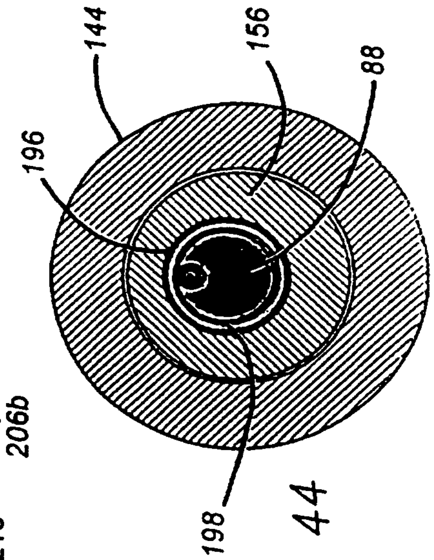

FIG. 44

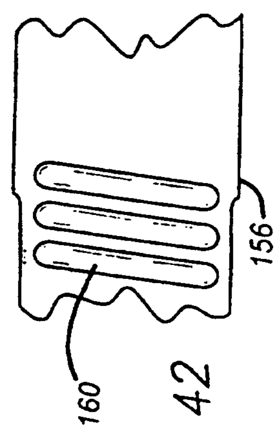

FIG. 42

INTERNATIONAL SEARCH REPORT

Inte. onal Application No
PCT/US 96/15927

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 41 36 861 A (KERNFORSCHUNGSZ KARLSRUHE) 13 May 1993 see column 2, line 37 - line 56 ---	1-99
X	DE 85 35 164 U (MASLANKA H) 27 February 1986 see page 4, line 37 - line 28 see page 6, line 23 - line 36 ---	1-99
X	WO 93 00048 A (SGRO JEAN CLAUDE) 7 January 1993 see page 6, line 12 - page 7, line 16 --- -/--	1,13,26, 33,44, 51,60, 70,87

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
23 January 1997	31. 01. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Gérard, B

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INTERNATIONAL SEARCH REPORT

Inter. nal Application No
PCT/US 96/15927

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 454 827 A (AUST GILBERT M ET AL) 3 October 1995 see column 1, line 22 - line 41	1,13,26, 33,44, 51,60, 70,87
X	US 4 243 715 A (GORDON MACK) 6 January 1981 see column 5, line 6 - line 21	13,26, 33,44, 51,60, 70,87
X	US 5 254 130 A (PONCET PHILIPPE ET AL) 19 October 1993 see column 2, line 60 - column 3, line 19	1
A	US 4 632 110 A (SANAGI KENICHIRO) 30 December 1986 see figures 1,2	
A	US 5 094 247 A (HERNANDEZ ERNESTO ET AL) 10 March 1992	
A	EP 0 288 309 A (ZINNECKER HAL P) 26 October 1988	
A	US 5 042 707 A (TAHERI SYDE A) 27 August 1991	
A	EP 0 521 595 A (LUNDQUIST INGEMAR H) 7 January 1993	
A	EP 0 609 182 A (XTRODE SRL) 3 August 1994	
A	US 5 415 158 A (BARTHEL THOMAS C ET AL) 16 May 1995	

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. onal Application No
PCT/US 96/15927

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
DE-A-4136861	13-05-93	NONE		
DE-U-8535164	27-02-86	DE-A-	3641935	19-06-87
		DE-A-	3704094	18-08-88
WO-A-9300048	07-01-93	FR-A-	2682877	30-04-93
		EP-A-	0544882	09-06-93
US-A-5454827	03-10-95	EP-A-	0684014	29-11-95
US-A-4243715	06-01-81	NONE		
US-A-5254130	19-10-93	AU-A-	4049193	18-11-93
		EP-A-	0636010	01-02-95
		JP-T-	7505801	29-06-95
		WO-A-	9320760	28-10-93
US-A-4632110	30-12-86	DE-A-	3530792	17-04-86
US-A-5094247	10-03-92	NONE		
EP-A-0288309	26-10-88	US-A-	5035248	30-07-91
US-A-5042707	27-08-91	NONE		
EP-A-0521595	07-01-93	AU-B-	660444	29-06-95
		AU-A-	1085892	20-08-92
		AU-A-	3295195	25-01-96
		CA-A-	2061215	16-08-92
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		US-A-	5315996	31-05-94
		US-A-	5322064	21-06-94
		US-A-	5329923	19-07-94
		US-A-	5454787	03-10-95
		US-A-	5477856	26-12-95
		US-A-	5228441	20-07-93
EP-A-0609182	03-08-94	US-A-	5482037	09-01-96
US-A-5415158	16-05-95	NONE		